Department of Veterans Affairs

Journal of Rehabilitation Research and Development

February 1995, Vol. 32, No. 1

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Veterans Health Administration
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We hope to open up an ongoing dialogue between professionals as a means of exchanging information and sharing diverse opinions among disciplines.

Editor
Tamara T. Sowell

CALL FOR PAPERS

We welcome submission of manuscripts in the fields of Prosthetics and Orthotics; Spinal Cord Injury and Related Neurological Disorders; Communication, Sensory and Cognitive Aids; and Gerontology. Guidelines for submission of manuscripts may be found on page ii.

Editor
Tamara T. Sowell

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Journal of Rehabilitation Research and Development
NOTICE TO CONTRIBUTORS

Purpose and Scope

The *Journal of Rehabilitation Research and Development,* published quarterly, is a scientific rehabilitation research and development publication in the multidisciplinary field of disability rehabilitation. General priority areas are: Prosthetics and Orthotics; Spinal Cord Injury and Related Neurological Disorders; Communication, Sensory and Cognitive Aids; and Gerontology. The *Journal* receives submissions from sources within the United States and throughout the world.

Only original Scientific Rehabilitation Research and Development papers (including Preliminary Studies) will be accepted.

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GUEST EDITORIAL

The March of Science

1994 marks the centenary of the birth of Norbert Wiener, a prolific and original mathematician and philosopher, who coined the term "cybernetics" to characterize the similarities of, and potential synergism between, humans and machines—the latter exemplified by the computers and servomechanisms of the 1940s and 1950s, which he observed during his long tenure on the Mathematics Department faculty at the Massachusetts Institute of Technology.

As I was to learn when I was asked in the mid-1980s to comment on his thin but prescient writings in this area (1), Professor Wiener envisioned his cybernetics as applying to issues of rehabilitation. He speculated on a limb-replacement prosthesis controlled by the brain of the amputee and was engaged in a project to present speech to deaf persons via vibration on the fingers.

As a Mechanical Engineering Department faculty member and design engineer, I was embarked serendipitously on a parallel path. I was exploring other applications of my missile power supply R&D of the 1950s (2), including external energy sources for servomechanism-driven joints in amputee prostheses (3).

The defining event of our confluence of interests was Professor Wiener's accident (a broken hip) in 1962, which put him in the Massachusetts General Hospital where our endeavor (the Boston Arm project) crystallized. My Master's degree candidate, Ronald C. Rothchild, conceived and implemented in a brilliant thesis an electronic, electrical, and mechanical realization of an above-elbow prosthesis (4).

Several design iterations later, the Liberty Mutual Insurance Company was fitting the limb, with some 500 applications to date, and the Boston design was complemented by the Utah Arm developed by my M.I.T. Ph.D. student, Stephen C. Jacobsen, enabling 750 above-elbow amputees.

I later learned that improved prostheses had not only been a goal in the post-World War II U.S.A., but also during the height of that conflict in Nazi Germany, a muscle-signal controlled hand (using electronic vacuum tubes!) had been developed, the precursor to the Russian Hand demonstrated in 1960.

Pasteur is reported to have noted "chance favors the prepared mind." While my student and I had studied the possible application of our missile power knowledge to prostheses, and by that time I had enjoyed several years of R&D to help ameliorate blindness (5), it was the happenstance of Professor Wiener's injury that thrust me into real musculo-skeletal products. The march of science is not the orderly linear progression some would make it out to be. And wouldn't Professor Wiener be delighted by the advances in assistive technology that have burgeoned during these past four decades!

Robert W. Mann, Sc.D.
Whitaker Professor Emeritus
Biomedical Engineering
Massachusetts Institute of Technology

Robert W. Mann, Sc.D.

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LETTER TO THE EDITOR

To the Editor:

Many thanks for this great honor and opportunity, especially for Vol. 31, No. 3, edited by my old friend, Ernest M. Burgess, M.D.

But now, I am an old man, and you should cancel my name. But your publications have been a great help during my professional life.

Sincerely yours,
Prof. Dr. med. Ernst Marquardt
Salzburg, Austria
Emeritus Professor of Orthopaedic Surgery
Heidelberg, Germany
Formerly with:
Orthop. Klinik und Poliklinik
der Universitat Heidelberg, Germany
Dysmelia Department and Technical Orthopaedics

The Editor Replies:

It was such a pleasure to hear from you and to know that you have been reading the *Journal* for so many years. I contacted Ernest M. Burgess, M.D. and Hans Richard Lehneis, Ph.D., both of whom have been Guest Editors of past issues of the *Journal,* as well as members of the Editorial Board, sending each a copy of your message to me. All three of us cannot accept your thinking of yourself as an "old man" knowing full well that you are still called upon professionally in an Emeritus capacity by people from all over the world, and asked for your expert opinion relative to management of persons with amputation.

We have not removed your name from our mailing list or from our minds. We would be pleased to receive critiques from you of some of the printed papers published in the *Journal,* which we could relay to the authors, and perhaps publish. Both the *Journal* and the authors would be extremely appreciative of, and interested in, your views. Thank you, Dr. Marquardt.

Tamara T. Sowell
Editor

Clinical Relevance for the Veteran

SUMMARY OF SCIENTIFIC/TECHNICAL PAPERS IN THIS ISSUE

Design of a Controlled-Energy-Dissipation Orthosis (CEDO) for Functional Suppression of Intention Tremors.

Michael J. Rosen, PhD; Allison S. Arnold, MS; Ivan J. Baiges, MS; Mindy L. Aisen, MD; Sheila R. Eglowstein, BS *(p. 1)*

Purpose of the Work. This design project was meant to produce a device that will allow people with arm tremors to undertake manual tasks with greater independence. The CEDO supports the user's arm and smoothes its motions much the way the suspension of a car reduces its bouncing. **Subjects/Procedures.** Evaluations were performed by subjects with tremors due to multiple sclerosis or traumatic head injury. Quality of movement was studied during functional activities and laboratory testing. **Results.** The outcome of the work is a prototype tremor-damping brace that mounts to a table or wheelchair frame and allows motion of the user's arm in a plane (e.g., over a desk). Useful reductions in tremor with little resistance to intended motions were observed for most subjects. **Relevance to Veteran Population.** A product based on this work could expand educational and vocational capabilities for veterans whose control over their limbs is impaired by tremor.
Michael J. Rosen, PhD

An EMG-Controlled Grasping System for Tetraplegics.

Shalini Saxena, MS; Slavica Nikolić, BS; Dejan Popović, PhD *(p. 17)*

Purpose of the Work. Due to a spinal cord injury (SCI), humans find themselves totally dependent on other people or devices for even the simplest tasks that are normally taken for granted. The device designed enhances grasping and other simple daily activities. Subjects with complete SCI at the C6 and C7 level, along with humans injured at higher cervical cord levels, who have retained wrist extension but have paralyzed fingers and thumb flexors, can benefit from this development. **Subjects.** Six. **Results.** Initial clinical tests showed that simple daily activities can be accomplished or improved when using the device compared to attempts without the assistive system. **Relevance to Veteran Population.** There are a fair number of veterans who suffered spinal cord injury at a high cervical level who may directly benefit from this approach, which, in general, can be further developed and used for other assistive systems.
Dejan Popović, PhD

Gait Parameters following Stroke: A Practical Assessment.

Herbert P. von Schroeder, MD; Richard D. Coutts, MD; Patrick D. Lyden, MD; Edmund Billings, Jr., MD; Vernon L. Nickel, MD *(p. 25)*

Purpose of the Work. To analyze the walking patterns (gait) of stroke patients using an electronic gait analyzer and to assess the changes with time. **Subjects/Procedures.** Forty-nine stroke patients and 24 control subjects were analyzed. **Results.** Stroke patients walked slower than controls; they took fewer steps per minute and spent more time with both legs on the ground at the same time. Patients' affected hemiplegic legs spent less time on the ground and more time swinging compared to their unaffected legs. Gait measurements improved with time following stroke, mostly in the first 12 months, but the unequal pattern of gait did not change over time. **Relevance to Veteran Population.** Abnormal walking was due to difficulty in moving the body over a weaker, less stable leg. Gait analysis can be important for documenting abnormalities and determining the effects of therapy after a stroke.
Herbert P. von Schroeder, MD

Establishment of Consistent Gait after Fitting of New Components.

Rowan D. English, DAppSc (P/O); Wendy A. Hubbard, BAppSc (PT), MAppSc (HM); G. Keith McElroy, MEd *(p. 32)*

Purpose of the Work. This project was undertaken to give an indication of the length of time required for a person with an amputation to become re-familiarized with an artificial limb following the substitution of a component or a number of components. **Subjects/Procedures.** A single subject, a man with a through-knee amputation, was assessed using a test prosthesis with two different knee mechanisms. Several parameters were measured and analyzed to determine when his gait had stabilized so that a decision could be made about the suitability of the knee mechanisms. **Results.** For the clinical situation, it was

found that at least 1 week of acclimatization was required before a decision could be made about the suitability of the knee component. For the purposes of research, however, it was deemed preferable for the subject to use a knee mechanism for at least 3 weeks to be sure the relevant gait parameters had stabilized. **Relevance to Veteran Population.** This study helps the prosthetist in clinical practice establish the length of time required for trial of new components in an artificial limb. It also indicates to the researcher that an altered prosthesis needs to be used for a reasonable length of time before detailed measurements can be taken. Also, this assists in the further testing of prosthetic components and the subsequent development of objective prescription criteria. This directly benefits the prosthetists and their clients.
Rowan English, DAppSc (P/O)

Conventional 4-Bar Linkage Knee Mechanisms: A Strength-Weakness Analysis.
J. de Vries, MD, Dsc *(p. 36)*

Purpose of the Work. The objective of the study done is to trace the relevant factors of 4-bar linkage knees which influence function, comfort, and cosmetics of the prosthesis. **Subjects.** None. **Procedures.** Using clinical and biomechanical research data, a strength-weakness analysis of eight 4-bar linkage knees has been carried out. **Results.** At the stance phase, five of the eight knees are intrinsically stable, meaning without extension of residual limb force. The 0° center of rotation of these knees is behind the femur-heel line. Each knee has its own collection of instantaneous centers of rotation (a trajectory) which begins with the 0° center of rotation. When bending the knee, the hip flexion-torque required is smaller when the 0° center of rotation is closer to the femur head-toe line and is dependent on the measure of the axial load. On average, a comparatively large amount of energy is still necessary. During the swing phase, the maximal axial stump load, the maximal hip-moment, and the energy required are approximately the same within the eight knees in relation to walking speed. Friction influences the swing characteristics of the prosthetic lower leg considerably. **Relevance to Veteran Population.** With the help of objective clinical and biomechanical features of 4-bar linkage knee mechanisms, the correct knee can be chosen for the individual patient.
J. de Vries, MD, DsC

Waking Effectiveness of Visual Alerting Signals.
Sherry K. Bowman, MClSc; Donald G. Jamieson, PhD; Robert D. Ogilvie, PhD *(p. 43)*

Purpose of the Work. People who are unable to hear acoustic alarm signals because they have a complete or partial hearing loss must rely on visual or tactile signals to warn them in the event of an emergency. However, there is debate as to whether personal smoke detector devices that provide a visual alarm can be relied upon to wake a person safely. We studied the alerting effects of visual alarm devices when people were in the deepest stages of sleep—slow wave sleep (SWS) and random eye movement (REM) sleep—and related our results to the physical (optical) characteristics of devices available to consumers. **Subjects/Procedures.** The brain activity of individual sleepers was monitored electrophysiologically over the course of a night's sleep. A calibrated visual alerting (strobe light) signal was provided after subjects were confirmed to be in a specified stage of deep sleep. The strobe was allowed to run until the subject awoke, or a maximum of 5 minutes elapsed. Twenty healthy, young adult women were tested repeatedly in this way. All reported that they were good sleepers, and had normal hearing and vision. None was taking medication. **Results.** Even under the favorable pharmacological (medication-free) and optical (smoke-free) conditions of the present study, sleepers did not wake consistently under the most intense testing conditions. We conclude that currently available devices of this type cannot be relied upon to wake a sleeping person safely, in the event of a fire. **Relevance to the Veteran.** Even with the most intense light signal tested, sleepers woke safely only about half the time. Deaf and hard-of-hearing veterans should, therefore, know that they cannot rely on devices of this type to wake them safely in the event of a fire.
Donald G. Jamieson, PhD

Department of Veterans Affairs

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Design of a controlled-energy-dissipation orthosis (CEDO) for functional suppression of intention tremors

Michael J. Rosen, PhD; Allison S. Arnold, MS; Ivan J. Baiges, MS; Mindy L. Aisen, MD; Sheila R. Eglowstein, BS
Eric P. and Evelyn E. Newman Laboratory for Biomechanics and Human Rehabilitation, Massachusetts Institute of Technology, Cambridge, MA 02139

Abstract—Conventional neurological practice is generally not successful in restoring independent upper extremity function to people with disabling tremors. The authors have been investigating an orthotic approach, the application of energy-dissipating loads to affected limbs, to allow voluntary intent to be expressed while attenuating tremor. CEDO 1 is a prototype Controlled-Energy-Dissipation Orthosis, which permits the 3 degrees of freedom (dof) needed for table-top activities. It mounts to the user's chair or table and applies velocity-proportional resistance to his/her forearm by means of computer-controlled magnetic particle brakes. The design incorporates a stiff linkage transmission to the elbow brake of the orthosis, allowing it to be fixed in the frame of reference. This eliminates its inertia from the moving linkage and provides virtually direct drive in all 3 dof. Initial experimental results show selective clinically significant tremor reduction during experimental tracking tasks.

Key words: *assistive technology, motor control, orthotics, rehabilitation engineering, tremor.*

INTRODUCTION

Tremor as a Clinical Problem

Pathological tremor is an involuntary rhythmic oscillation of the limbs, head, or trunk which affects an estimated one million Americans today (1). In its mildest form, pathological tremor impedes activities of daily living (ADL) and hinders social function. In more severe cases, however, tremor occurs with sufficient amplitude to obscure all underlying voluntary activity. For the large fraction (65 to 70 percent) of tremor-disabled individuals who have tremor in their shoulders, elbows, wrists, or hands, independent function is difficult or impossible (2).

The work described in this paper is directed specifically toward the management of action or "intention" tremor. This type of movement disorder is elicited or aggravated when the limb is involved in a voluntary motor task distinct from postural maintenance (3–6) and is commonly associated with damage to the spino-cerebellar and mid-brain centers that interact to coordinate purposeful movements (1,2). Head injury, multiple sclerosis (MS), Friedreich's ataxia, Joseph's disease, and some strokes and tumors can cause intention tremor. It may also arise from neurological degeneration caused by chronic alcohol intoxication or metabolic poisoning (3).

The most effective treatment available today for tremor-disabled individuals is medication used on a trial-and-error basis (3,6). Because clinicians cannot reliably predict an individual's response to a particular drug, it is standard procedure for clinicians to prescribe, in the order of decreasing expected effectiveness, the drugs known to reduce tremor. When a drug fails to provide relief, the dosage is altered or the next drug on the list is prescribed. Even when a drug does reduce tremor, its benefits must outweigh its undesirable side effects and potential for addiction before it is prescribed on a long-term basis (7). Common side effects of tremor medications include sedation, weight gain, nausea, diarrhea, rash, impotence, and depression (2).

Address all correspondence and requests for reprints to: Michael J. Rosen, PhD, Department of Biomedical Engineering, University of Tennessee, 899 Madison Avenue, Memphis, TN 38163.

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Application of Mechanical Loading to Tremor Management

The difficulties with drug treatment of tremors have motivated the authors' work on functional limb loading. Rosen et al. have shown experimentally that people with abnormal intention tremor are disabled not because they lack useful levels of volitional control or adequate muscular strength, but because the magnitudes of their superimposed pathological oscillations approach the magnitudes of their purposeful actions (8–10). This suggests that if a loading orthosis could be designed to selectively suppress tremor while allowing voluntary movement, it would enable individuals with tremor to perform some daily tasks independently.

Encouraged by one-degree-of-freedom (dof) wrist tremor experiments in which viscous loads did selectively attenuate intention tremor (8,11) and by the theoretical rationale for tremor-suppression orthoses outlined below, Rosen et al. have more recently begun a program of designing and building active and passive devices capable of measuring tremor in multiple dof while simulating a variety of loads including inertia, elasticity, damping, rigid walls, force perturbations, and combinations of the above (10–18). All of these systems can be viewed as emulators or prototypes of tremor-suppression orthoses and assistive interfaces, and one of them—the CEDO 1 (Controlled-Energy-Dissipation Orthosis)—is the focus of this paper. CEDO 1 is a prototype 3-dof restraint system meant to enable tremor-disabled individuals to undertake a particular set of daily activities independently (12). In this paper, the design and initial human-subject testing of CEDO 1 is described and important design goals for tremor-suppression orthoses are discussed.

Theoretical Arguments for a Tremor-Suppression Orthosis

Three broad classes of hypothesized mechanisms are considered by most investigators as likely to play a role in generating or influencing the properties of normal physiological and pathological tremors to varying degrees:

1. biomechanical resonances, in which the limb oscillates at a tremor frequency related to its lumped passive mechanical properties and is forced by muscle noise that originates in a background of random motor unit firing or by cardioballistic oscillations (19–26);
2. reflex loop instabilities, in which neuromuscular transmission delays and/or increased gains reduce the phase margin of both segmental and transcortical reflex arcs, causing oscillation (27–30);
3. central nervous system (CNS) oscillators, in which autonomous sources in the CNS drive the affected muscle groups to produce oscillatory forces at fixed frequencies and amplitudes regardless of peripheral factors (13,31–35).

It may be shown qualitatively that achieving selective reduction in tremor (relative to voluntary movement) by means of viscous damping is a reasonable expectation for any of these three hypotheses. If a tremor is caused by biomechanical resonance, the addition of a parallel damper to the anatomical inertia and elasticity driven by the muscles will increase the damping ratio of the system and will thereby diminish the amplitude of its resonant peak. If a tremor is driven by an oscillatory reference signal from the CNS, then the damper to ground (the proximal limb segment) presents a 1/s load to the force measured at the limb and effectively attenuates the tremor relative to slower purposeful movement frequencies by 20 dB per decade of frequency difference. Finally, if an autonomous reflex oscillation is responsible for tremor, the "physical plant" driven by the closed-loop neural system is a series element in that loop. If damping alters the dynamics of that plant appropriately, it could reduce the tendency to oscillate.

Evidence from Experimental and Clinical Loading Devices

Many investigators have modified normal physiological tremor by altering mechanical conditions at the distal end of the tremorous limb. However, most of these studies have been directed specifically toward defining the tremorogenic mechanisms of physiological tremor (20–22,24,32). Very few studies have focused on pathological tremors (13,35–37), and the majority of these have been devoted to identifying mechanisms of pathological tremor, not to determining the effectiveness of loading as a basis for assistive technology.

The authors know of just two published studies other than their own in which damping loads were applied to the limbs of tremor-disabled persons specifically for the purpose of tremor management. Morrice et al. (38) applied mass loads, spring loads, and damping loads across the wrists of subjects with cerebellar ataxia in 1987 and discovered that the damping loads consistently improved subjects' accuracy in 1-dof tracking tasks. Sanes et al. (39) applied constant force loads, mass loads, and damping loads to the wrists of subjects with postural and action

tremors in 1988 and reported that the damping loads reduced subjects' tremors dramatically.

With regard to existing orthoses, the concept of using fixed-base orthotics to modify the performance of the human arm is not new. *Active* multi-dof experimental orthotics—such as the Case Western Reserve University "Arm Aid," a 5-dof exoskeletal robot meant to manipulate a paralyzed human arm (40); the Rancho Los Amigos Hospital "Electric Arm," a similar device which was actually developed into a commercial product (41,42); a remotely driven electric arm orthosis developed at the New York University Institute of Rehabilitation Medicine (43); the so-called man-amplifiers reviewed by Kazerooni (44); and teleoperators, robotic devices whose motion is controlled by an operator at a distance (45,46)—received considerable attention 2 to 3 decades ago. However, these systems were uniformly too complex in design, too demanding of the user, and cosmetically too obtrusive to be successful as orthotic devices for tremor-disabled users in daily activities. In contrast, the commercially available Mobile Arm Support, or "Ball Bearing Feeder" (47), is commonly used today to provide low-friction arm support for people with deltoid muscle paresis or paralysis. With regard to tremor management, Michaelis Engineering of Southampton, England has more recently developed and is commercially marketing two viscous-loading assistive devices—a feeding aid for tremor-disabled individuals called the "Neater Eater" and a computer mouse Tremor-Reducing Apparatus called the "MouseTRAp" (48). At the time the CEDO project was begun, however, the task remained to incorporate damping into a general-use orthosis that would meet realistic product-design goals.

METHODS

Design Goals for Tremor-Suppression Orthoses

The goals and constraints which determined the configuration and main features of CEDO 1 include:

- tremor reduction and selectivity of tremor reduction
- safety
- compatibility with anatomy and function
- comfort and ease of use
- economy

Other goals which, because of insufficient research or market information, were not used as a basis for designing CEDO 1, but which are expected to influence the success of tremor-suppression orthoses in the future include:

- minimization of fatigue
- minimization of long-term decrease in effectiveness
- minimization of negative after-effects of use
- reliability
- cosmesis

Goals which drove the CEDO 1 design features are discussed below as part of the description of those features. Goals which relate instead to user-device system performance are discussed in the context of the results from the initial subject testing.

Features of CEDO 1

Device Summary

CEDO 1, pictured in **Figure 1**, is a 3-dof computer-controlled energy-dissipating orthosis. It generates resistive loads by means of magnetic particle brakes whose torques are transmitted to the forearm of the user via a stiff low-inertia linkage. CEDO 1 was designed as a prototype assistive device for persons disabled by tremor, meant to

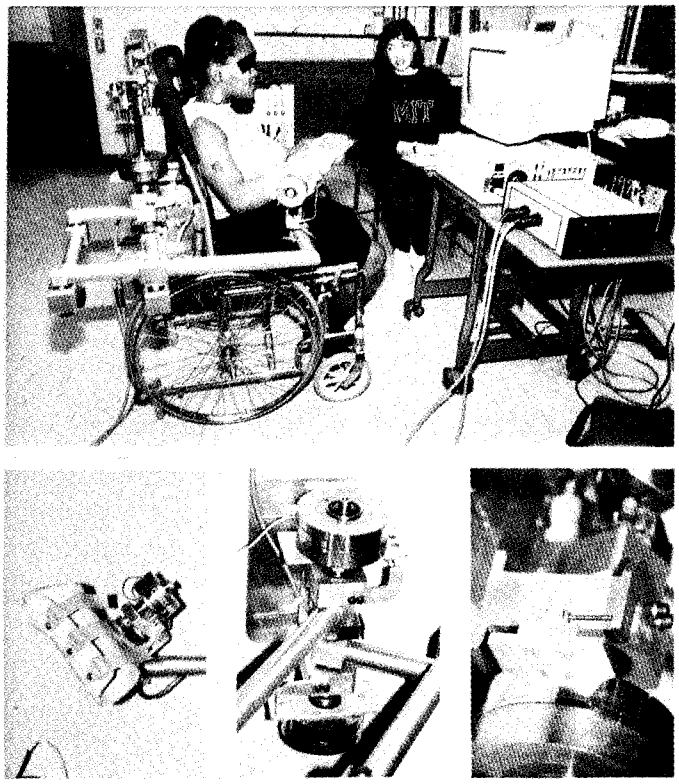

Figure 1.
a) CEDO 1, mounted on a standard wheelchair, undergoing experimental evaluation; b) wrist cuff and magnetic particle brake for distal limb tilt; c) magnetic particle brakes for damping in movement plane, mounted on base plate; d) flexure bearing for accommodating small runout of the brake shaft.

be evaluated by its intended users in abstract and functional tasks, and to generate improved designs. In research terms, CEDO 1 was built to validate the working hypothesis that velocity-dependent resistive loads can suppress intention tremor in more than one dof without unacceptably attenuating voluntary movement.

The main components of the CEDO 1 system are shown schematically in **Figure 2.** The forearm of the user is secured to the device via a rigid plastic cuff and Velcro straps. Potentiometers mounted at the three orthosis axes measure the forearm position, and differentiator circuits housed in an electronics box determine its velocity. These analog position and velocity signals are converted to digital signals via an analog-to-digital (A/D) converter, and the digital signals, in turn, are fed to a computer. To make CEDO 1 behave as a damper at the attachment to the user's arm, a computer program reads the position and velocity information and calculates the brake torques needed to generate a resistive force proportional to the user's velocity. Finally, the computer's digital torque commands are converted to analog signals via a digital-to-analog (D/A) converter, and the analog signals control the brake-driver circuits to activate the brakes.

Kinematic Configuration

Design of a tremor-suppression orthosis to accommodate unlimited function of the upper extremity would impose several classes of constraints on the device. These include:

1. Kinematics. The limb coupling of the orthosis must be able to attain any position and orientation of which the limb is capable via any trajectory.
2. Anatomical compatibility. The structure of the orthosis must not occupy volume intersecting with the space filled by the user's limb or other body segments.
3. Absence of singularities. The position and orientation of the limb coupler must uniquely determine the values of all other kinematic state variables of the orthosis.
4. Dynamics. The resistance imposed on the user's limb by the orthosis during the performance of functional movements must not exceed the sustained force and torque capabilities of the user.
5. Accuracy. The designed-in and incidental loading characteristics (e.g., inertia and Coulomb friction) of the orthosis must not unacceptably degrade the positioning accuracy of the user's limb.
6. Task environment compatibility. The mechanism of the orthosis must not interfere with objects with which the user interacts when undertaking personal, vocational, educational, or recreational tasks.

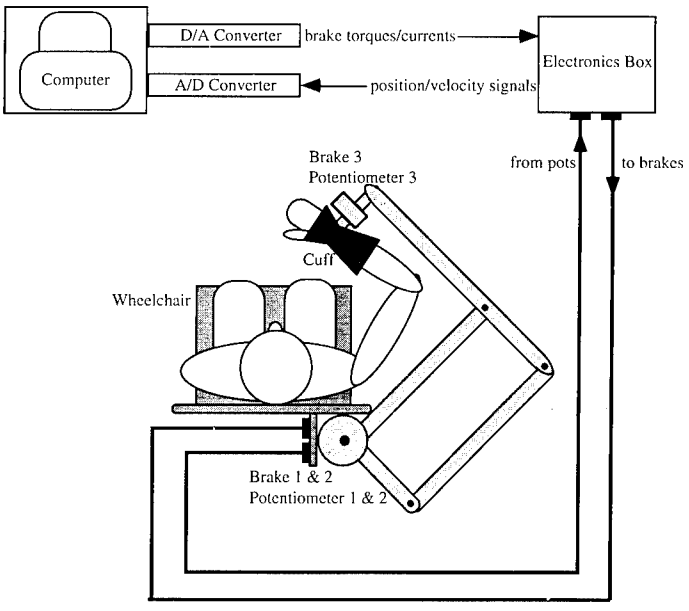

Figure 2.
Schematic of the CEDO 1 system.

In the CEDO project, a decision was made to loosen these constraints by pursuing a more limited geometry and a smaller set of functional tasks. Our goal was to significantly reduce tremor in the performance of desktop and tabletop tasks; that is, in the interaction with objects in a horizontal volume of space over a surface: (i.e., "desk," reading, and eating) activities similar to those with which a standard mobile arm support is meant to be compatible. Thus, CEDO 1 was given the 3 dof shown in **Figure 3.** The first and second dof permit the user to move the midpoint of the forearm in a horizontal plane. The third permits the user to tilt the forearm about a horizontal axis perpendicular to the long axis of the forearm, shown as A-A in the figure. CEDO 1 also allows the user to pivot his/her forearm in the horizontal plane about an axis perpendicular to the forearm but this dof is not damped.

Three kinematic configurations were considered for achieving the horizontal planar motion of the two first dof:

- a Cartesian orthosis: one with two orthogonal prismatic (linear) joints defining x and y axes
- an R-Θ orthosis: one with a fixed-base revolute joint on which a prismatic joint provides a second, linear dof

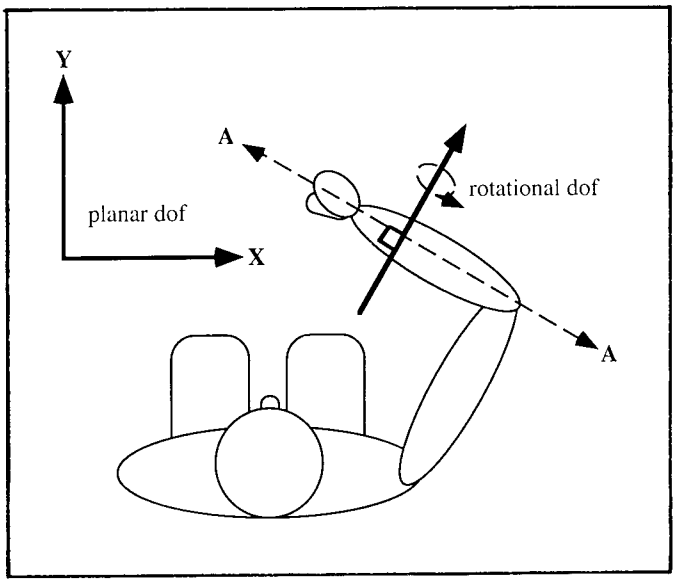

Figure 3.
CEDO 1 degrees of freedom.

- a Φ-Θ orthosis: one which consists of a two-bar open kinematic chain whose state is defined by two angles.

The third (tilt) dof was allocated to a distal revolute joint in all three approaches.

A Φ-Θ configuration was selected for CEDO 1 for several reasons. First, it has the same kinematic structure as the widely used mobile arm support, so its compatibility with a range of tabletop upper limb function has, in effect, been confirmed by naturalistic experiments. Second, the Φ-Θ configuration does not require linear joints. Endpoint stiffness would have been more difficult to achieve when transmitting loads through linear bearings than through revolute joints. Finally, the use of readily available (rotary) magnetic particle brakes to produce damping would have required one or two linear-to-rotary transmissions in the alternative designs and thus would have eliminated the desirable characteristics of direct drive. The CEDO 1 configuration is an "effectively direct-drive" design which avoids many of the problems associated with conventional transmissions such as belts (or cables or metal bands) and pulleys or a gear train. All of these would have introduced backlash, or a "dead zone" within which orthosis endpoint movement unloaded by the brakes would have been possible. Most would also have introduced friction substantially in excess of that contributed by the bearings, adding a finite breakaway force to the load function applied to the limb of the user. The only disadvantage of having used a direct drive system is that no step-up of the brake torques was obtained. This resulted in bigger brakes and/or lower endpoint damping than would have been possible with torque-multiplying transmissions.

Actuator Location

Two variations of the Φ-Θ orthosis are shown in **Figure 4;** both have the same kinematics, but the first configuration requires that the linkage "carry" one brake (defined from this point on as "brake 2"). Given that the various alternative damper technologies all have substantial mass (the selected particle brake weighs 12 lb), the user of an orthosis with the first configuration would feel a considerable endpoint inertia. The altered configuration on the right, chosen for CEDO 1, has brake 2 fixed in the external frame of reference with its shaft coupled to link 1 via a 1:1 linkage transmission consisting of links 4, 3, and the extension of 1. The joints and links of this transmission affect the inertia at the endpoint far less than the moving brake of the first configuration. The shafts of the two brakes are colinear but independent.

Sizing and Materials of Links

The dimensions and geometry of the CEDO 1 linkage are shown in **Figure 5.** Link sizes were based on fabrication of simple mockups to determine the minimum dimensions required for elbow clearance by a large user during tilt movements at various endpoint positions. The link material, 6061-T6 aluminum tube stock, was selected for its economy, availability, ease of fabrication, and low inertia. Wall thickness (0.13 in/0.33 cm) and outer diameter (1.5 in/3.81 cm) were specified to meet stiffness criteria for transmitting damping loads in the horizontal direction

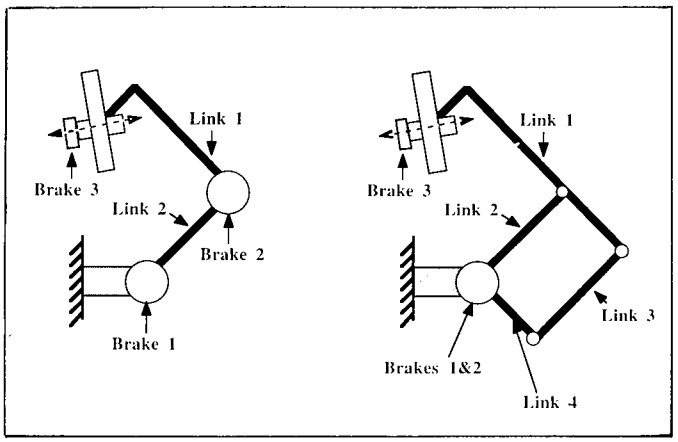

Figure 4.
Actuator relocation for CEDO 1.

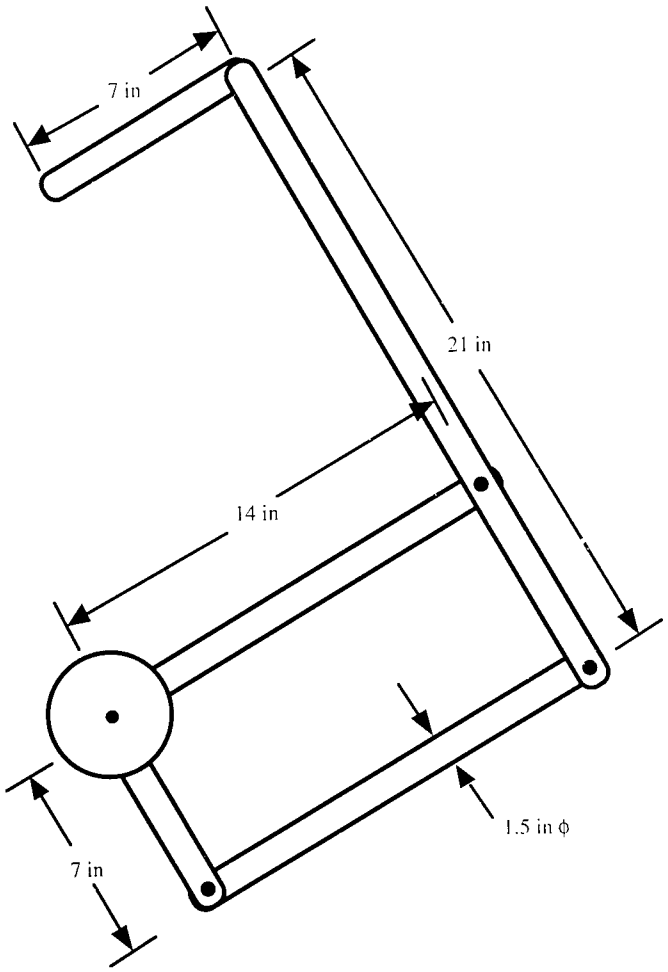

Figure 5.
Dimensions and geometry of the CEDO 1 linkage.

and for imposing rigid restraint in the vertical direction. Selected dimensions include a 50 percent safety factor against yield in any direction under conditions of expected worst case loading.

In the horizontal direction, compliance between the user and brake 2 posed a special concern. Recognizing that the orthosis itself would inevitably interpose inertia and elasticity between the user and the brakes, the orthosis was modeled as a grounded dashpot in series with a spring and a mass. Then, in the context of this model, the stiffness (K) and mass (M) of the orthosis were constrained by two concerns. First, if the damping value were allowed to approach $\sqrt{KM}/2$, the energy dissipation of the orthosis would be comparable to its energy storage and the orthosis could resonate. Given a desired maximum damping value, this problem could be avoided by maximizing stiffness and/or mass. Since it was also desirable to keep the resonant frequency $\sqrt{K/M}$ well above the tremor frequency—and because of concerns regarding muscle fatigue and overall device weight—the logical approach was to maximize stiffness while minimizing mass. The current CEDO 1 design has a measured (at $\Theta = 90°$) horizontal stiffness of 39,300 N/m for linkage 1,3,4; a calculated effective mass of 4.1 kg for the same mechanical system; and a measured (at the endpoint) maximum damping constant of 90 N/(m/s) for brake 2. Since this damping constant is less than $\sqrt{KM}/2 = 200$ N/(m/sec), the system cannot resonate and the dynamics design goal is met.

In the vertical direction, ad hoc experiments and consultation of the anthropometrics literature (49) led to the specification of a worst case downward load of 50 lb (22.7 kg) and a maximum deflection of 0.2 in (0.51 cm). Although the measured stiffness of CEDO 1 actually does not meet this specification—a 40 lbf (18.1 kgf) load produces a deflection of 0.5 in (1.27 cm) with the orthosis in its most extended configuration and 0.3 in (0.76 cm) with $\Theta = 90°$ (links 1 and 2 perpendicular)—it does meet the deflection specification under typical loads applied by tremor-disabled users. The greater-than-expected deflection measured in the vertical direction stems from play and compliance in the bearings and joints not accounted for in the original static stiffness calculations.

Finally, the interface of the links with the revolute joints was designed to avoid stress concentrations. Each bearing block (see **Figure 1**) incorporates a hollow plug with a tapering cross section onto which the tubular link slips. The junctions were machined to a slip fit and filled with Loctite 680.

Actuators and the Force-Velocity Colinearity Issue

Safety was given a very high priority in the design process and consequently only passive torque sources were considered for CEDO 1. This decision was pivotal in constraining other aspects of the CEDO design and performance, most specifically the relationship between kinematic configuration and the colinearity of force and velocity at the endpoint. Although active devices (e.g., DC motors or hydraulic actuators) would permit a broader range of loads to be evaluated, only passive sources cannot under any circumstances move the user's limb. Redundant safety features could certainly be built into an active torque system like the Adelstein manipulandum (14), but limit-setting functions add expense, are not perfectly reliable, and do not eliminate the (valid) perception that the system could fail unsafely.

Magnetic particle brakes were selected for the CEDO 1 actuators for the above safety reasons and because:

1. Unlike mechanical dampers, they are readily computer-controlled.
2. They are much less expensive than hydraulic actuators and their required valves.
3. They lack the undesirable series-compliance of pneumatics.
4. They require less maintenance than brakes which use friction surfaces in contact.
5. They are characterized by higher power-to-weight ratios than DC motors or hydraulic actuators, important in a system with direct drive.
6. They are a familiar technology with which the authors' laboratory has considerable experience (8,13).

The two large brakes at axes 1 and 2 (Placid Industries, Inc. model B150P-06) have a maximum voltage of 6 volts, a maximum current of 1.8 amps, a rated power of 11 watts, an electrical resistance of 3 ohms, a de-energized drag of 30 oz-in (2.16 kg-cm), an unforced response time (i.e., without speedup circuitry) of 130 ms, and a maximum output torque (60 percent greater than its continuous torque rating) of 250 lbf-in (288.0 kgf-cm). The small brake at axis 3 (Placid Industries, Inc., Lake Placid, NY, model B15P-24) has a maximum voltage of 24 volts, a maximum current of 250 mA, a rated power of 6 watts, an electrical resistance of 105 ohms, a de-energized drag of 5 oz-in (360 g-cm) an unforced response time of 25 ms, and a maximum output torque of 35 lbf-in (40.3 kgf-cm).

As mentioned above, force-velocity colinearity—the ability to generate a resistive force vector along the line of action of the velocity vector—is a desirable property for a tremor-suppression orthosis. Because of the disadvantages associated with alternative kinematics and the high priority given to safety, the current CEDO 1 design was pursued despite the fact that it is *not* characterized by colinearity for all endpoint locations and directions of movement. The absence of colinearity in this prototype should allow, through experiments currently underway, determination of the extent to which non-colinearity is acceptable. A geometric demonstration of the non-colinearity properties of CEDO 1 follows.

In **Figure 6,** an idealized sketch of CEDO 1 is presented with Θ at an indeterminate angle greater than 90°. Throughout this analysis and **Figures 6** and **7,** the line between the base joint and the endpoint is always drawn parallel to the long axis of the page. This is meant to emphasize that the base angle (Φ)—the rotational position of the whole orthosis—is irrelevant; it simply rotates the sectors of colinearity and non-colinearity derived here.

In **Figure 6a,** the sign of Θ-dot was chosen arbitrarily as positive (orthosis elbow flexing) and the sign of Φ-dot was chosen as negative (proximal link rotating clockwise). The purely resistive torques T_Θ and T_Φ generated by the brakes at the joints act in directions *opposite* to Θ-dot and Φ-dot as shown in the figure. The two velocity vectors, V_Θ and V_Φ, drawn at the CEDO endpoint, represent the local endpoint velocities resulting from pure rotation at one joint or the other. The two force vectors F_Θ and F_Φ represent the forces generated at the endpoint as a result of each of these one-joint rotations and are drawn in the directions in which they impinge on the limb of the user.

The directions of F_Θ and F_Φ bear explanation. F_Θ is aligned with the orthosis axis, the line joining the CEDO endpoint and the base joint. The force generated by a torque at Θ with the Φ brake off *must* be in this direction because

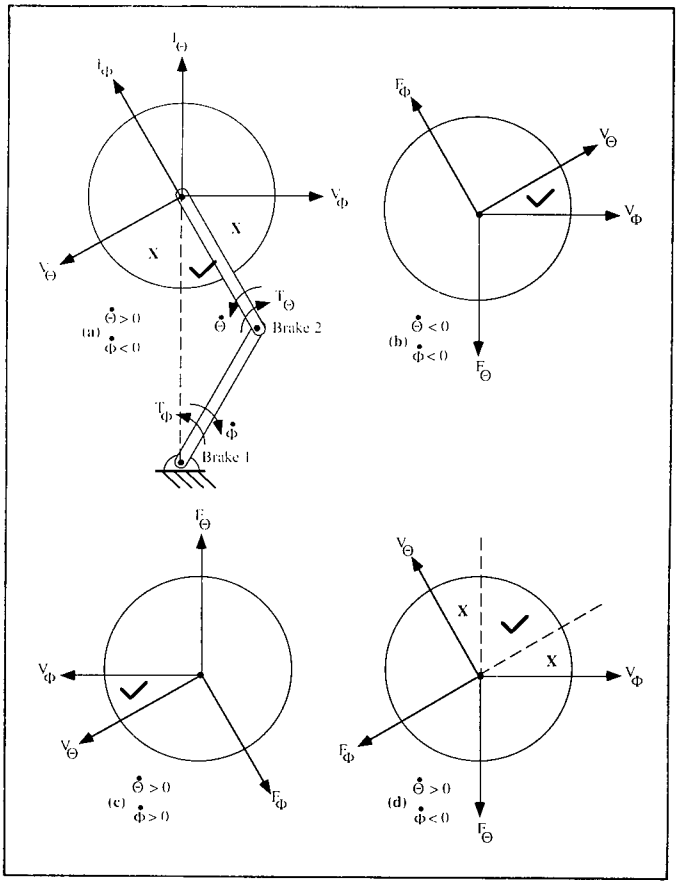

Figure 6.
Force and velocity contributions from the two joints for the four combinations of angular velocity direction.

a component in any other direction would require a moment about the base joint. By the same reasoning, F_Φ must be aligned with the distal link since a component in any other direction would imply the existence of a moment at the elbow joint, a moment which is impossible without torque at the elbow. Note that these arguments are completely general and do not depend in any way on the values of Θ or Φ.

The force the user feels, given the specified rotational directions, must lie within the angular sector defined by the extensions of F_Θ and F_Φ. For given endpoint velocities, its actual direction depends only upon the relationship between the damping constants of the two brakes. The critical observation is that the range of net force directions at the endpoint (in **Figure 6a**) is narrower than the range of possible movement directions which result from the same combination of joint rotations. This implies that whenever the endpoint movement direction falls outside the zone indicated with a check, the resistive force vector cannot be aligned with the endpoint velocity vector.

Parts b, c, and d of **Figure 6** repeat this analysis for the three other combinations of rotation direction. In **Figure 7,** colinearity circles are presented for two extreme cases of CEDO configuration to illustrate the observation that endpoint distance from the base joint has a dramatic effect on the relative sizes of colinear and non-colinear zones.

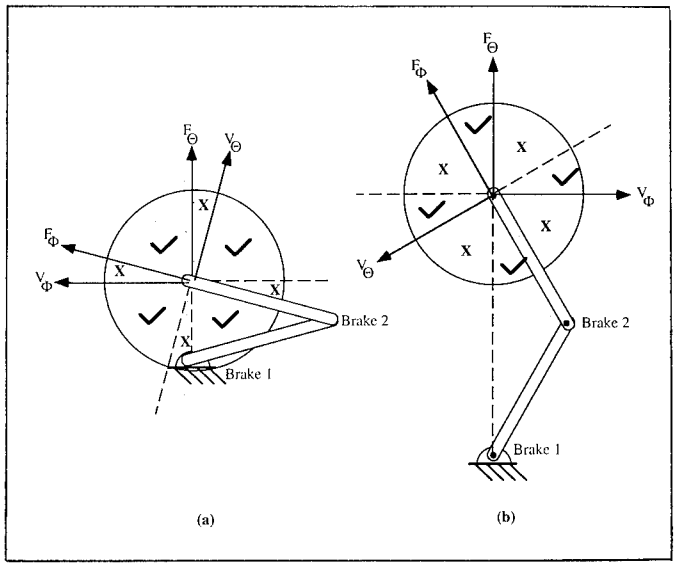

Figure 7.
Non-colinearity diagrams for very extended and very flexed CEDO 1 configurations.

Flexure-Bearing Brake Mounts

The brake mounts depicted in **Figure 1** are flexure bearings meant to accommodate small runout (deviations from straightness) of the brake shafts. The base joints of links 2 and 4 (the proximal links which couple to the brake shafts) incorporate pairs of tapered roller bearings *in addition to* the bearings in the brakes. This was necessary since the bearings of the brakes were insufficient to transmit the expected radial loads to ground. As a result, however, the brakes could not be rigidly mounted to ground. The short segments of welding rod, shown in **Figures 1c** and **1d,** deflect relatively easily to accommodate the (barely perceptible) wobble of the brakes, while providing much higher stiffness in compression and tension to transmit the brakes' functional reaction torques to ground.

Limb Coupling

The primary issue considered in the limb coupler cuff design was comfort. The cuff-skin contact area had to be large enough to prevent uncomfortable pressure concentrations, yet conforming enough to prevent excessive compliance. Further, the position of the orthosis had to be designed so that the user would not be compelled to accept an uncomfortable position or sustain muscular effort to avoid it.

The cuff and dovetail joint pictured in **Figure 1** are used to transmit the resistive loads of the CEDO to the forearm of the user and to prevent wrist flexion/extension and forearm pronation/supination. Three different-sized cuffs, Ali-Med Wrist-Hand Orthosis, Models #5842, 5844, and 5846 (Ali-Med, Inc., Dedham, MA) are available to comfortably accommodate a variety of short-term experimental subjects. The dovetail joint allows the attachment between the cuff and the CEDO 1 linkage to be adjusted easily between a point very close to the wrist and a point more proximal on the forearm of the user. For future tests of functional use, it may be necessary to custom-form a cuff for each user. Using the current design, some subjects in preliminary studies reported (typically after an hour-long testing session) that the cuff felt too tight. It has also become apparent that the point at which the cuff supports the forearm is too distal for some subjects who must maintain shoulder muscle activity, particularly deltoids, to keep their elbows from dropping.

Another concern regarding limb coupler design is the presence of soft tissue: the muscle forces that generate tremor are directly applied to the skeleton, while practical orthotic restraint systems are limited to applying their loads through the skin. In effect, CEDO 1 must transmit damping forces through an anatomical series spring, and as a result,

the thickness and compliance of the soft tissue layers set a lower limit on the amplitude to which tremor can be reduced. While this limit can be minimized by applying external loads through limb sections where the soft tissue layer is relatively thin and stiff (e.g., the dorsal surface of the hand or the bony prominences of the wrist), this approach may conflict with comfort issues. Estimates of the stiffness of the current limb coupler and underlying soft tissue (15) suggest that at the maximum damping loads, CEDO 1 will allow a deviation of 5.5 mm between the distal CEDO joint axis and the user's wrist joint, below which tremor amplitudes cannot be damped.

Circuits and Sensors

The CEDO 1 circuitry and sensors serve two functions. First, to obtain the angular position and angular velocity signals needed for control and data collection, the three joints of the orthosis are instrumented with conductive plastic 1 percent linear potentiometers. The potentiometer outputs are conditioned by analog circuits, and the conditioned signals input to practical operational amplifier differentiators to obtain angular velocity signals. Second, to generate the current to activate the brakes, three brake-driver circuits, essentially voltage-controlled current sources which include lead compensation to account for the response times of the brakes, are used. All DC voltages needed for the CEDO 1 circuitry are provided by a 110-watt switching power supply.

Control Algorithm

CEDO 1's damping action is controlled through software using feedback of joint angles (it has no endpoint force transducer). All software was developed on a Leading Edge model D2 AT-compatible computer configured with an 80287 math coprocessor, an EGA enhanced graphics display adaptor, a Data Translation DT2814 A/D converter, a MetraByte DAS-8 A/D converter, and a MetraByte DDA-06 D/A converter. The MetraByte A/D board has an Intel 8254 programmable interval timer which is used to generate the 60 Hz control cycle signal. A flow chart for the CEDO control algorithm is shown in **Figure 8.**

Step 1 in the control algorithm is to read from files data required to set the endpoint damping to the desired value. In step 2, timer initialization sets clock and counter parameters for the control cycle. In step 3, position signals from the three potentiometers and velocity signals from the analog differentiator circuits are digitized, converted into physical units, and input to the control algorithm. In steps 4 and 5, a model of the CEDO 1 kinematics is employed to calculate endpoint position and endpoint velocity from the measured joint positions and computed joint velocities and to determine the brake torques needed to produce the desired endpoint force. In step 6, the sign of the required power at each joint is checked. Because the CEDO 1 is equipped with energy-dissipating brakes, not motors, it cannot meet a positive power requirement and therefore cannot produce a resistive force vector aligned with endpoint velocity for certain directions and certain CEDO linkage configurations. If positive power is required at a joint, the brake torque at that joint is set to 0. In step 7, the torque-current curves of the brakes (obtained by fitting second-order polynomial equations to torque-current data from the brake manufacturer's specification sheets) are used to determine the brake current needed to generate the joint torques computed in steps 5 and 6. Finally, in step 8, analog signals representing the desired current for each brake are sent via the D/A converter to the brake-driver circuitry. The control algorithm continues until a set num-

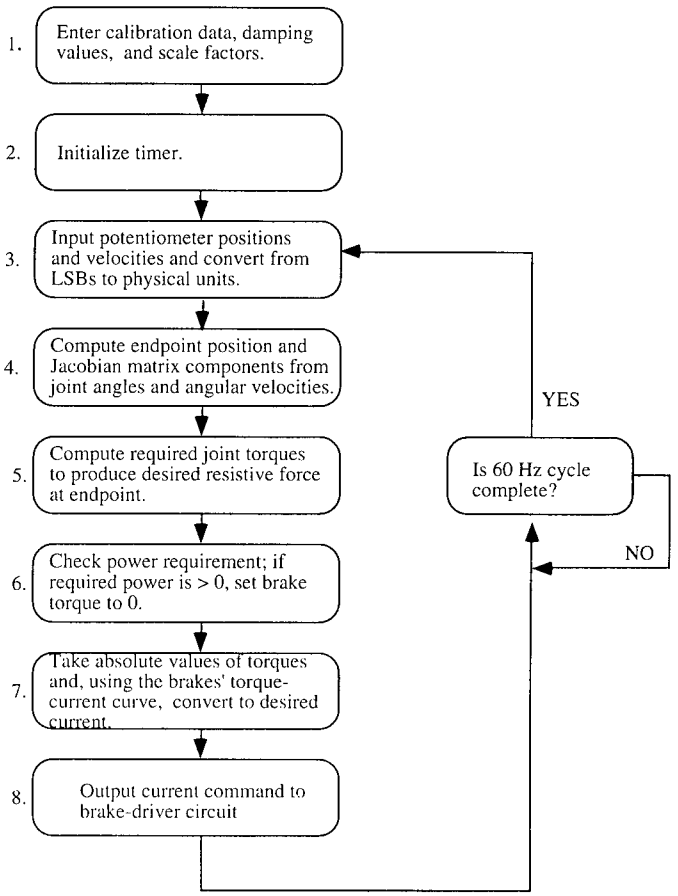

Figure 8.
Schematic of the CEDO 1 control algorithm.

ber of loops have been completed or until the user presses a key on the keyboard to terminate the control program.

RESULTS

Tremor Reduction Effectiveness

The primary goal of CEDO 1 is, of course, to reduce tremor by a functionally significant factor. The standard for complete success is reduction to the amplitude of physiological tremor. For improvements short of this ideal, "How good is good enough?" depends on the activities the user wishes to be able to undertake independently (with orthotic support) and on his/her personal tradeoffs between functional benefit and the various costs of using the CEDO. An individual whose financial independence and personal satisfaction depended, for example, on performing electronic assembly tasks would impose tighter specifications for tremor reduction on the CEDO than someone whose primary need was to turn pages. Further, since the CEDO is meant to be used in functional activities by individuals whose tremors are present during voluntary movement, it must attenuate abnormal movements relative to voluntary movements. This means that an objective evaluation of the effectiveness of the orthosis must also reflect the extent to which the user's actual movements represent his/her intent.

Ongoing experiments with tremor-disabled subjects have demonstrated that viscous loads applied by CEDO 1 can significantly and selectively attenuate upper-limb intention tremor. Preliminary results from an early subject tested by author Baiges are presented below, and a more extensive report is found in Arnold, et al. (50).

Subjects using CEDO 1 were asked to perform pursuit tracking tasks. These tasks served two purposes. First, because they required subjects to perform specific motor acts, the tasks induced the subjects' intention tremors. Second, the tasks permitted the subjects' voluntary movements to be distinguished from their involuntary movements under the assumption that motions linearly related to the target were voluntary and motions not linearly related to the target were involuntary. (Given the frequency separation between the target frequency range and tremor frequencies, harmonics of the target frequencies, if present in the subject's movements, are small relative to noise due to tremor.)

During a tracking task, two markers were shown on a computer screen, a target that moved along a pre-programmed trajectory, and a response that moved as the subject's arm moved. Subjects were asked to move their limb so that the response marker coincided with the target marker as accurately as possible. Targets for the tracking task were generated by summing five sine waves with frequencies below 0.41 Hz (well below the expected 2–4 Hz tremor frequencies) in 2 dof. Movements of the CEDO 1 linkage in the left-right direction corresponded to movements of the response marker in the horizontal or X direction, and movements of the CEDO 1 linkage in the front-back direction corresponded to movements of the response marker in the vertical or Y direction. The mapping between subjects' movements in space and the response cursor's movements on the screen was scaled such that the subjects worked within a 20 cm by 15 cm area. During an experimental session, trials were done at four different levels of damping. Each trial lasted one minute, and each level of damping was repeated three times per session in three different sessions. The order of the trials within each session was random. Subjects were encouraged to practice at the beginning of each test session, to rest between trials as needed, and to ask questions or make comments about CEDO 1 and its damping loads. Target and response trajectories from each trial were sampled at 60 Hz and stored for subsequent data processing.

Results from the tracking experiments are shown in **Figures 9** and **10**. While these data were collected on one 34-year-old woman with severely disabling intention tremor due to chronic progressive MS, the results are representative of the results obtained thus far from other subjects and other etiologies. In **Figure 9**, typical target and response trajectories in the X and Y directions (in units of actual movement) are plotted versus time for each damping level. The tremor amplitude is clearly reduced with the addition of damping, falling from approximately 5 cm peak-to-peak in the undamped trial to less than 1 cm peak-to-peak in the highest damped trial.

In **Figure 10**, data averaged over trials from all three test sessions are shown processed in the frequency domain. Each plot was generated by first computing the auto-and cross-power spectral densities of the target and response trajectories for the X and Y components from each trial using the Welch method of power spectral estimation. Then the coherence function was used to subtract from each response spectrum the component of the response linearly related to the target. Finally, the residual tremor spectra from all trials at a given damping level were averaged. As indicated in the figure, tremor peaks which appear at frequencies near 1 and 2 Hz in the X and Y undamped power spectra are substantially attenuated in the damped power spectra.

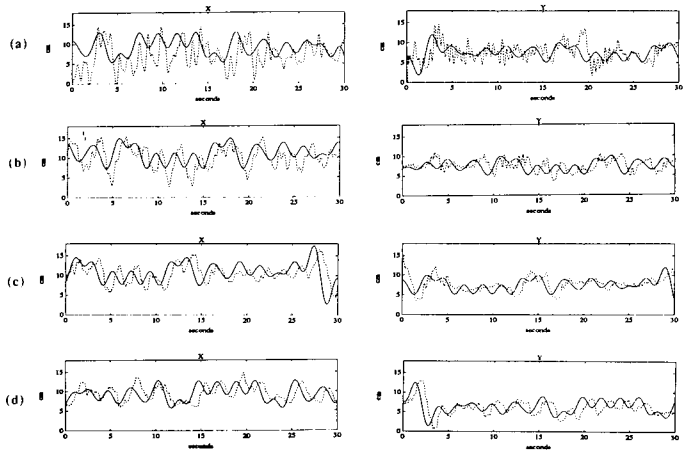

Figure 9.
Target and response time trajectories in the X and Y directions for (a) no damping, (b) low damping, (c) medium damping, and (d) high damping.

A measure of tremor power was also obtained for each trial by computing the area under the tremor power density curve between 0.6 Hz and 3 Hz (the frequencies which bound the subject's tremor band) and averaging tremor power measures for all trials at a given damping level. Compared to the undamped tremor power, the damped tremor power values were reduced by approximately 65, 83, and 85 percent for low, medium, and high levels of damping, respectively.

Finally, the magnitude and phase of the transfer function relating the target and response trajectories, averaged over the target frequencies, were examined to monitor the selectivity of the tremor reduction. These results verified that while the subject's tremor was diminished significantly in the damped trials, the subject's tracking performance was not significantly hindered. In the X direction, the transfer function magnitude remained constant although the subject lagged the target an additional 30° on average in the most damped trials. In the Y direction, the average transfer function magnitude *increased* with the application of damping while the phase remained relatively constant.

User Comments

All subjects tested to date have offered positive remarks on the effect of damping. Typical comments include: "I feel more comfortable with damping"; "My tremor is much worse without damping"; "More damping!"; and "Damping helps me do the tracking task better." In contrast, few of the subjects have been able to envision

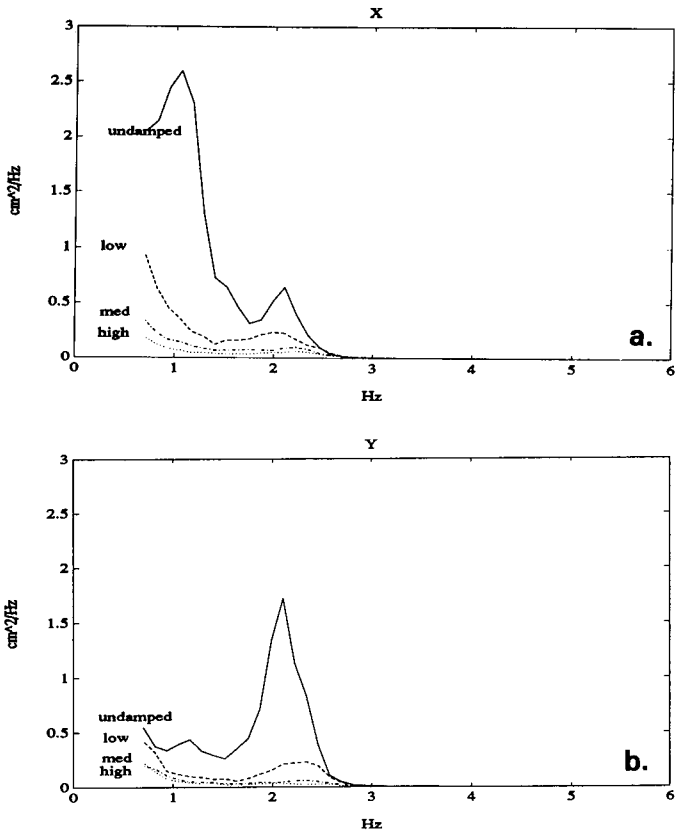

Figure 10.
Averaged tremor power spectra in the X and Y directions for no damping, low damping, medium damping, and high damping.

a commercial orthotic device that would be useful in reducing tremor in a functional setting. The authors believe this reflects the unfamiliarity of the subjects with the notion of mechanical approaches to tremor management and also the non-idealities of the current design.

Subjects' awareness of the non-colinearity of the present CEDO design have varied in an apparently systematic way with the severity of their tremors and the level of damping. When asked to remark on the 'feel' of CEDO 1 and any changes with damping level, the subjects with the most severe tremors made no comments that indicated that they had noticed the non-colinearity or had been bothered by it. Subjects with less severe tremors and non-disabled control subjects noticed nothing remarkable at damping levels up to 35 N/(m/sec), while for higher damping levels they commented on sensations of lumpiness or jerkiness, whose end point position-dependence suggested that they were aware of locations where the non-colinearity was worst.

Conjecture and Observations on Short- and Long-Term After-Effects

To provide a basis for design optimization, detailed experimental data must be gathered on the mechanisms of tremor; the effects of loading; and the relationships between tremor, loading, and the physiology of fatigue and strengthening. More specifically, a physiological understanding of why damping loads attenuate tremor and how they might cause undesirable (*or* desirable) fatigue effects, 'carryover' effects, or strengthening effects from daily use is essential for designing better, more effective tremor-suppression orthoses. Future testing of the CEDO should provide not only the additional data needed to test the effectiveness of the orthosis as a product in ADL, but should also allow the following hypotheses about fatigue, carryover, and strengthening effects to be tested experimentally.

Potential Fatigue Effects

When using CEDO 1, the user's musculature is required to produce three classes of forces: those normally required for intended movement to overcome the impedances and external forces imposed by the limb and the environment; those necessary to move the *orthosis* at the frequencies of the voluntary activity; and those associated with tremor. The onset and development of fatigue depends on the populations (not necessarily distinct) of muscle fibers meeting each of these force requirements, the levels of force required of each population, their fatigue properties, *and* on how all these characteristics vary among tremor types. While there is considerable literature on the metabolic mechanisms of muscle fatigue (51) and on the fatigue characteristics of fiber types I, IIa, and IIb (52,53), there are very few publications on the specificity of involvement of distinct fiber types in pathological tremors or on how normal fiber recruitment patterns are altered by tremorogenic pathologies. Edstrom (54) and Shahani and Wierzbicka (55) have reported some observations of motor unit recruitment and fiber type involvement in Parkinson's disease, essential tremor, spasticity, and cerebellar ataxia, but detailed facts are unavailable. Fatigue effects may also be influenced by the mechanism by which tremor is attenuated. If tremor is centrally driven and tremorogenic muscle torques are undiminished by the presence of damping, for example, fatigue may occur at a different rate than if the applied damping effectively compensates oscillatory reflex dynamics such that the tremor torques themselves are reduced.

CEDO 1 has not yet been used in experimental sessions which approximate a full work day. Rather, experimental sessions to date have run 1.5 hours at most, during which the ratio of tracking time to rest time was 1 to 3 and the duration of each experimental trial was from 30 to 60 seconds. A consistent observation from such sessions is that subjects often describe themselves as being tired when the session is over. One should recognize, however, that virtually all of the subjects were unaccustomed to being physically active due to their disability and that they probably would have found the tracking tasks to be as tiring (or *more* tiring) without damping, that is, it seemed to be limb use in general that the subjects found tiring. In future investigations, the CEDO will be used in ADL during which muscular fatigue is monitored more carefully, perhaps by recording surface myoelectric activity (56,57).

Potential Carryover Effects

A question often raised by clinicians with regard to tremor-suppression orthoses is whether 'carryover' effects might occur immediately after decoupling the limb of the user from the orthosis. To date, no experimental evidence for either a sudden aggravation of tremor or a prolonged attenuation of tremor immediately following the withdrawal of an energy-dissipating load has been reported, nor have data been published which suggest that tremor is generated by a physiological regulator which is adaptive (i.e., one that makes parametric adjustments to maintain a reference level of tremor in spite of external changes which tend to diminish it).

In experiments with CEDO 1 thus far, evaluation protocols have not yet focused on detecting and quantifying beneficial or detrimental after-effects of its use. However, certain related observations have been made. None of the objective performance data analyzed to date have indicated a statistically discernible trend toward increase or attenuation of tremor over the course of a multiple-day series of trials; in other words, use of the CEDO on day i was not consistently followed by higher or lower tremor on day i + 1. One subject did show a dramatic reduction in tremor following the first five or six trials of each session. The protocol did not, however, allow a distinction to be made between a physiologically-mediated tremor-reduction after-effect of damping and other possible effects such as fatigue, (re)familiarization with the tracking task, or hypothetical 'warm-up' effects of the CEDO itself.

Potential Strengthening Effects

A possible longer term result of using the CEDO on a daily basis is related to its incidental function as an exercise device. If CEDO 1 increases the strength of the loaded muscles, then its tremor reduction effectiveness *may be diminished* over time by increasing the forces generated by a given level of tremorogenic motoneuron activity. The potential for such a strengthening effect may depend upon the mechanism by which loading affects tremor; loading which only diminishes movement resulting from unaltered rhythmic muscle force might alter muscular strength differently than loading which reduces muscle force oscillations themselves.

The authors have found no literature to date which explains the long-term effects of pathological tremor on muscle strength or the interaction between exercise physiology and tremor physiology. The literature on muscle response to exercise, however, does make it possible to state explicitly the conditions which must be met for prolonged use of the CEDO to yield muscle changes which decrease its effectiveness. First, to attain the increase in fiber diameter necessary for increased strength, the fast-twitch glycolytic IIb muscle fibers must be recruited during short duration high-intensity exercise (like weightlifting). Lower intensity sustained exercise (like long-distance running) does not increase strength, but rather improves endurance by increasing the number of mitochondria in the I and IIa muscle fibers and by improving the microcirculation around these fibers (58). Diminished effectiveness of the CEDO from extended use would thus require movement with the CEDO requiring force levels sufficient to exercise the IIb fibers, thereby increasing their strength, and larger amplitude tremor resulting from strengthened IIb fibers (i.e., IIb fibers playing a role in tremor movement and, when strengthened, producing higher forces *from the same level of tremorogenic efferent neural activity,* as opposed to just increasing the maximum IIb force level). If these conditions are not met, prolonged use of the CEDO might actually prove favorable if endurance is increased by exercising type I fibers or if strength is increased (countering disuse atrophy or degeneration) by exercising type II fibers in a manner that does not increase tremor amplitude.

Another issue related to strengthening is the phenomenon of fiber type conversion, that is, the documented change in the contractile properties of fast-twitch fibers to slow-twitch characteristics in response to sustained electrical stimulation (59) and the apparent change in the proportion of more fatigue-resistant IIa fibers relative to IIb fibers in endurance-training athletes. If there is an advantageous relationship between the latter effect, any specificity of fiber type involvement in tremor, and any specificity of fiber type strengthening by viscous loading, then the possibility exists that the strengthening effects of a tremor-suppressing orthosis would be *favorable* by means of another mechanism. This too must be the focus of extended-use experiments with the CEDO.

Economy

Estimating an acceptable range for purchase price for a product which provides the functional gains of the CEDO is in part a matter of guessing the policies which third-party payers would adopt if such a product became a reality. A reasonable approach is to identify upper and lower bounds by noting the costs of existing products which are in various ways comparable. Examples include:

1. the standard (passive, free-moving) mobile arm support such as the Jaeco Friction Controlled Arm Positioner priced at $175 (Jaeco Orthopedic Specialities, Hot Springs, AR);
2. an adjustable (passive, rigid) leg orthosis for training which can be found for $700 to $900;
3. a continuous passive motion device for upper extremity therapy which costs approximately $2,500;
4. an above-knee prosthesis which costs anywhere from $2,500 to $20,000 including the fitting and component selection services of a prosthetist;
5. a typical powered wheelchair, which ranges in price from $1,700 for a 3-wheeled scooter to $3,800 for a standard-configuration chair to $10,000 for a unit with extra features, such as special interfaces and power-adjustable seating.

These benchmark prices suggest that a CEDO should be marketed for between $2,500 and $5,000 in order to align with pricing of comparable products. Based on the approximate costs of systems, materials, and labor for fabrication of CEDO 1, it appears that the technology required to produce functionally significant tremor reduction could be sold for a price the market will accept.

Cosmesis

An informal survey of assistive technology presently on the market will quickly reveal that it is difficult to define even a conventional wisdom regarding the appearance of

products for users with disabilities. The recent growth in consumerism among members of this market segment emphasizes that, like the population in general, the consumers of assistive technology assign importance to—and show the same diversity of preference with regard to—the aesthetic impact of what they use. Commercialization of the CEDO, if it is successful, will require careful identification of distinct market segments within the population of tremor-disabled potential customers.

In the absence of any formally-gathered market data, the design of CEDO 1 was guided by a few generic notions of what constitutes acceptable appearance. Other factors being equal, the appearance of a design is improved by being visually and auditorily unobtrusive; by having a look and feel similar to other technology in the user's environment; by avoiding an intimidating or hazardously technological appearance to the user and to those around him or her; and by contributing to a look of dignity, competence, and seriousness of purpose of the user.

DISCUSSION AND FUTURE PLANS

The outcome of this project was the completion, characterization, and initial human-subject testing of CEDO 1, a prototype fixed-base 3-dof orthosis for functional attenuation of intention tremor. Early data collected in 2-dof tracking tasks with tremor-disabled subjects indicates that CEDO 1 can produce sufficient tremor attenuation with sufficient selectivity to permit independent function in some activities which would be impossible without assistance. Further, the apparent success of CEDO 1 was accomplished with commonplace materials and components. A design using off-the-shelf particle brakes, standard aluminum alloy, no force-sensing, and a conventional linkage configuration has apparently met our initial goals, and it has done so with absolute safety.

CEDO 1 is, of course, not an outcome at all in the sense that research and development based on it are ongoing. Most obviously, experiments are planned to test its objective effectiveness with clinically homogeneous groups of subjects with a tremor disability. It is also clear from observing preliminary users that a mechanical design change is needed at the arm cuff to clear the space between the arm of the user and functional tabletop tasks. The most obvious alternative is to suspend the coupler and the user's arm below the orthosis so that little or no mechanism intrudes between the splint and the table surface. In addition, mounting the CEDO base at the front of a user's desk (i.e., *across* from him/her rather than behind and to one side) will allow a more flexed state of the orthosis for the most frequent endpoint positions, mitigating the effects of force-velocity colinearity. Finally, the CEDO 1 loading characteristics themselves must also be subjected to more detailed engineering characterization. If the endpoint is moved through a known controlled time course, will the endpoint forces required to produce that trajectory be predictable from a dynamic model? Do the brakes need altered compensation to improve the simulation of viscous damping?

Once CEDO 2 has been built with these and other altered characteristics, functional evaluation will be undertaken in ADL settings for extended periods. This beta testing will not only provide the additional data needed to test the effectiveness of the orthosis as a product, but also allow the authors' hypotheses about fatigue and exercise effects to be tested experimentally. Finally, a professional approach to market research will be necessary to firmly establish the demand for CEDO, to test the likelihood of third-party reimbursement, and to determine how best to make tradeoffs between competing product features and how the answers to these questions vary among identifiable market segments. This will need to be an ongoing process as new approaches to financing assistive technology are put in place, as new entitlement and civil rights legislation is written, and as consumers with disabilities continue to make themselves heard in the marketplace.

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An EMG-controlled grasping system for tetraplegics

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Abstract—A two-channel, portable, battery operated, functional electrical stimulation (FES) system with surface electrodes to enhance grasping in tetraplegics was developed and tested. This system is meant for tetraplegics capable of grasping by tenodesis. Candidates for this system must retain some wrist extension, and have paralyzed but innervated finger flexors, and nearly normal shoulder and elbow coordination within the working space. The control signal that turns the stimulation of forearm finger and thumb flexors on and off is based on the detection of the threshold of the amplified, rectified, and integrated electromyographic recordings using surface electrodes positioned over the wrist extensors. The voluntary contraction of wrist extensors is suitable for triggering the stimulation, and it is reproducible enough for daily home use. The new device was tested on subjects with tetraplegia, and the general conclusions are: 1) the system increases the strength of the grasp; 2) no side effects or related problems were noticed; 3) the training period is short; 4) the reliability of the operation is good; and, 5) the design of the analog part of the system allows its easy integration into a computerized device. Functional tests of the system showed that some of the study subjects did not benefit from this approach due to disuse and denervation types of muscle atrophy of their finger flexors, lack of controllable wrist extension, curled resting position of distal and proximal interphalangeal (IP) joints, and/or inability to bring the thumb in the opposition of fingers.

Key words: *EMG control, grasping, tetraplegia.*

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INTRODUCTION

Functional electrical stimulation (FES) can restore limited control over absent or abnormal function in persons who have suffered spinal cord injury (SCI). In persons with tetraplegia, FES can provide grasping by external control of the paralyzed muscles in the forearm and hand (1). The Case Western Reserve University (CWRU) fully implantable FES device is the only one used for the assistance in daily living functions (2). The functional evaluation of the CWRU system has shown that there is substantial improvement in simple grasping tasks (3). More than 25 such systems are in use around North America. The CWRU system is meant for subjects with tetraplegia who retain some voluntary elbow flexion and extension, innervation of some forearm and hand muscles, and limited or no wrist control.

Wrist motion is essential for augmenting the fine motor control of the fingers and hand (4). Positioning of the wrist in the direction opposite that of the fingers alters the functional length of the digital tendons so that maximal finger movement can be attained; this is called tenodesis. Conversely, some flexion of the wrist puts tension on the long extensors, causing fingers to open automatically and aiding full finger extension. The wrist extension is caused by two groups of muscles: 1) extensor carpi radialis longus and brevis (extension of wrist, radial deviation); and 2) extensor carpi ulnaris brevis (extension of wrist, ulnar deviation). The range of wrist movement required for normal functioning is 10° flexion and 35° extension (5). This range was determined to be necessary for the following seven functional activities: lift glass to mouth, pour from pitcher, cut with knife, lift fork to mouth, use telephone receiver and push-button dialing, read newspaper, rise from chair; and seven personal care activities (touch

of head occiput and vertex, shirt neck, chest, waist, sacrum, and shoe). When the wrist was immobilized, the best performance was achieved having the wrist in a 15° extension (6).

Some persons with tetraplegia retain wrist movement and are able to grasp using a tenodesis. However, the grasp generated with a tenodesis is rather weak, and heavier object handling (e.g., opening a door, picking up a camcorder battery or VCR tape, holding a book, etc.) is frequently not feasible. In addition, in order to hold an object by using tenodesis, it is necessary to maintain the wrist extension during manipulation, and this is difficult or even impossible. Subjects who are able to use tenodesis for limited grasping typically have innervated finger flexors, but they are not controllable volitionally. The hypothesis tested in this research was that a rather simple system of myoelectric control signals from the same extremity can improve the grasping function by enhancing the flexion of fingers, including the control of a thumb position. In order to develop such a system, it is necessary to answer two questions: 1) What is the best location to record myoelectric activity? and 2) Which muscles and nerves are to be stimulated to elicit functional movement that enhances tenodesis grasp?

The literature dealing with this problem describes several possible approaches. FES systems to allow grasping can be divided among the origin of control signals to trigger or regulate the stimulation pattern: 1) shoulder control (7–9); 2) voice control (10,11); 3) respiratory control (12); 4) joystick control (1,2); and, 5) position transducers (13–15). A division can be made upon the method of delivering patterned electrical stimulation: 1) one to three channels to different muscle groups via surface electrode systems (14–16); 2) multichannel surface stimulation system (11); 3) multichannel percutaneous systems with intramuscular electrodes (7,10,12); and 4) fully implanted systems with epimysial electrodes (2).

Prochazka (15) suggested a very similar system that uses a wrist-controlled sensor to trigger the stimulation of muscles enhancing tenodesis grasp in a device called the Bionic Glove (patent pending). A glove with the sensor detects wrist movements and sets both the parameters of stimulation of each of three channels and the range of extension and flexion to turn the stimulation on and off. The glove contains the stainless steel mesh contacts for surface stimulation with conductive polymer-based electrodes. A microcomputer built into the battery-operated unit controls three channels of stimulation of the finger and thumb flexors and the thumb extensors. Everyday tuning of both the level of stimulation and the thresholds for control is automatic and requires only a voluntary wrist movement from neutral position to the maximal extension.

Since the introduction of myoelectric or electromyographic (EMG) control to limb prostheses, there have been many attempts to use myoelectric signals for the control of prostheses with multiple degrees of freedom (17–19). These attempts have been prompted because persons with high-level arm amputations frequently need multifunctional artificial arms but have limited muscle sites that are practical as myoelectric signal sources. The most successful myoelectric artificial limbs, below-elbow myoelectrically controlled hands, such as, the Utah artificial arm (20) and the Otto Bock myoelectric hand are in daily use.[1]

The EMG is a convenient control signal, because it does not need external energy, its activity follows the grasping process naturally, and eventually it will be possible to implant a system that will include both the stimulation and the recording electrodes. In this study we investigate the feasibility and preliminary functionality of an EMG-controlled FES grasping system applied to persons with SCI. This device employs surface stimulation of the finger flexors, and it is practical, portable, simple to don and doff, and easy to master.

The study was divided into four contiguous phases: 1) off-line analysis of the control signals; 2) design of the hard-wired electronic circuitry; 3) synthesis of the grasp; and, 4) testing of the device in tetraplegics.

OFF-LINE ANALYSIS OF CONTROL SIGNALS

The goals of this part of the study were to determine a processing technique suitable for control of the electrical stimulation of muscle nerves and to test the reliability of the device in subjects with tetraplegia.

Subjects

Six neurologically complete SCI subjects, between 20 and 45 years of age, were selected for the study from a group of 12 volunteers classified as complete or incomplete C4 to C6 levels. The volunteers were screened in an initial testing session to verify the presence of voluntary wrist movements (extension and flexion), voluntary control over biceps and triceps muscles function, normal passive range of movements, stability while sitting, and that the subjects had preserved ability to grasp using the tenodesis. The test

[1] Personal phone communication with Mr. Pike, November 1993.

included electrical stimulation of the forearm finger flexor muscles with surface electrodes using a custom-built stimulator. This test showed how a specific patient tolerates pain and discomfort (if any), and how the stimulation affects the wrist movements. The stimulating electrode (cathode) was positioned as close as possible to the wrist, while the anode was positioned at the middle of the forearm. The thenar muscle group was used for thumb flexion control. All subjects signed the informed consent approved by the local ethics committee.

The initial screening eliminated 6 of the original 12 SCI subjects for one or more of the following reasons: 1) limited or no response to stimulation (two subjects); 2) involuntary tremor while generating maximal voluntary contraction (MVC) of wrist extensors (two subjects); 3) lack of wrist extensor control (two subjects); and, 4) curling of the IP joints in the neutral position of the hand (three subjects).

Methods

The signals were recorded using three surface, disposable, self-adhering electrodes with 3.2 cm diameter (Encore Plus, Uni-Patch Inc., Wabasha, MN 55981), QT-5B low-noise preamplifier (Leaf Electronics, Edmonton, Alberta), and custom-designed biopotential amplifier (M. Gauthier, Edmonton, Alberta). The data were digitized at 10 kHz using an ADC 2838 (Data Translation, MS, USA) expansion board in a PC-IBM compatible computer (Gateway 2000-66E). The digital processing of the recorded signals included full wave rectification and low-pass filtering (21). We used DADiSP software (DSP Development Corporation, MA, USA) for the processing and analysis of these amplified, rectified, integrated, and smoothed EMG signals.

Results

All study subjects were asked to elicit MVC of their wrist extensors, maintain it for about 2 seconds, and then relax. This procedure was repeated in all subjects for several minutes during at least five sessions. The aim was to determine a reproducible, easy-to-elicit signal that can serve as the trigger for the commencement, as well as for the termination, of the stimulation of forearm finger and thumb flexors.

The EMG recordings depend upon the placement of the electrodes, skin, and electrode impedances (**Figure 1**). However, the analysis of the processed recordings in the same subject in day-to-day sessions, when mounting electrodes at more or less identical positions (the electrode positions were marked at the skin), showed a producible pattern of EMG recordings. No two EMG signals are identical: both amplitude and frequency spectrum vary. The rectified and amplified EMG recording always has a visible peak when the subject elicits and maintains a strong voluntary muscle contraction compared to the recordings made when resting the wrist extensors. The variability, even though very great (**Figure 1**), is not significant, as only a threshold method is adopted for control.

The effect of muscle fatigue has to be taken into account (**Figure 2**). During about 30 minutes of testing in the same subject, the peak of the integrated rectified EMG signal (RMS $\approx$ 100μV) dropped to about 60 percent compared to its maximal value (RMS $\approx$ 250μV) at the beginning of the test (22).

The use of the threshold method of the integrated, rectified, and amplified EMG signal emerged as an effective control signal. This strategy follows the adopted approach of voluntary control of turning the stimulation of

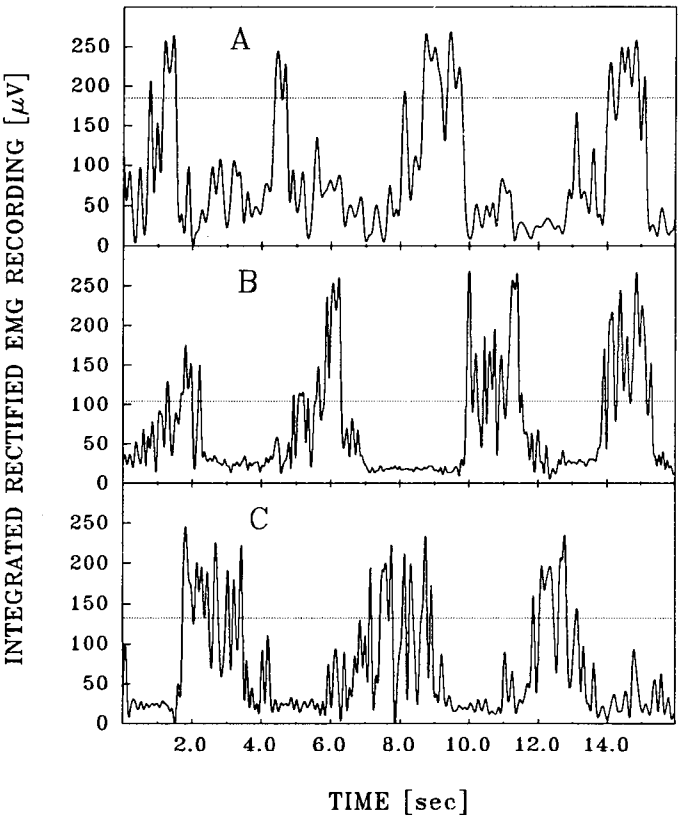

Figure 1.
The EMG from several consecutive contractions of three different subjects. Each of the recordings has a different threshold (dotted lines), showing that even though the activity varies from subject to subject, it is plausable to use the threshold method for triggering.

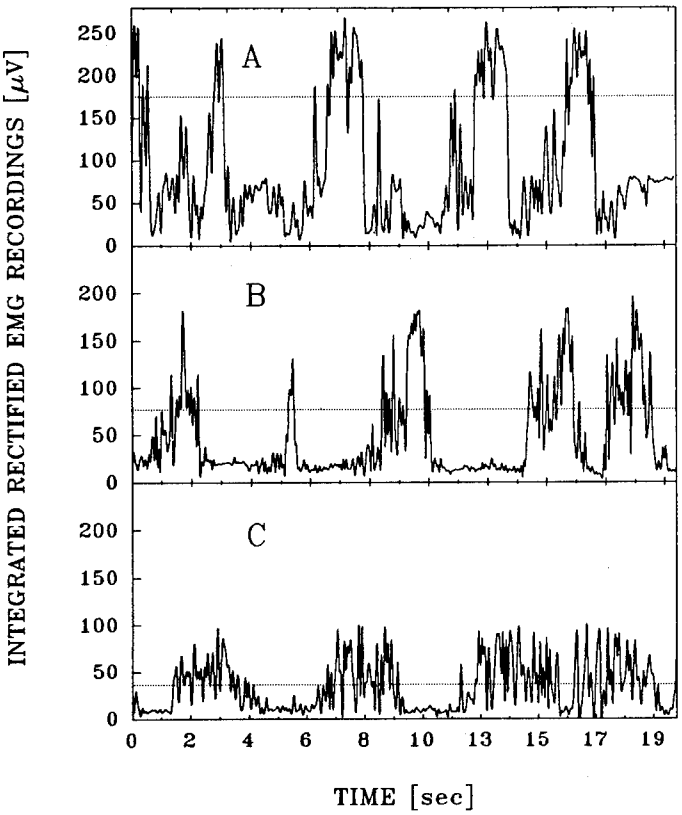

Figure 2.
The recordings from one untrained tetraplegic subject (C5/C6, complete lesion), 7 years after injury. The recordings show three short intervals from a long recording session (≈ 30 min). The top trace is from the first minute, the second is from the 15th, and the bottom one is from the last 20 seconds.

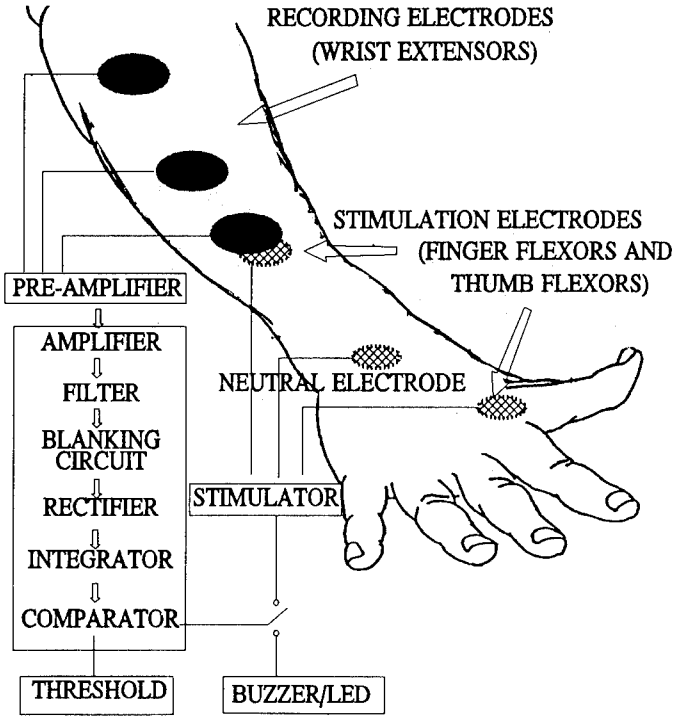

Figure 3.
The block diagram of the portable, battery operated recording and two-channel stimulation system. The first stage of the device includes a low-noise, high-common-mode-rejection ratio preamplifier. Optical isolation is used to separate the stimulating and the recording parts of the device. The stimulator controls the blanking device to ensure that the stimulation artifact and evoked potential are eliminated from the integrated EMG. The threshold level selection is realized with a simple voltage divider, and can be set any time during the operation. Visual (LED) and audio feedback (buzzer) are parts of the system to allow the setting of the threshold prior to functional use.

finger and thumb flexors on and off. The volar side of the forearm was found to be an appropriate location for recording when applying a system that uses an enhanced tenodesis for grasping, because it was possible to eliminate stimulation artifacts when the dorsal side of the forearm was stimulated.

DESIGN OF THE ELECTRONIC CIRCUITRY

Based on the off-line analysis using a bench system, a battery operated, portable, low-power device was designed (**Figure 3**). Three recording electrodes, described above, were connected to a custom-designed preamplifier characterized by a low-noise, high-impedance, high-common-mode-rejection ratio (CMRR). This preamplifier has a pair of junction field effect transistors (JFET) at the input, followed by the instrumentation amplifier (CMRR > 100 dB, A = 100, fε100–10,000 Hz). The signal was fed to a cascade consisting of a response-conditioned (RC) high-pass filter with gain (f > 100 Hz, A = 100), a full-wave precision rectifier, and a blanking device. The blanking device switches the output of the amplifier to the ground when the stimulation pulses are delivered to the appropriate motor nerves. The blanking period is adjustable in the range of 100 μs to 20 ms. During the blanking period the input to the integrator is zero.

The signal was then binary integrated, with 10 ms intervals, and fed to the input of a comparator. The second input of the comparator can be set to a predetermined voltage level at any time during operation. Once the integrated EMG crosses this threshold level, the comparator output goes "high." This control signal changes the state of a flip-flop that triggers the stimulator. The following

MVC resulting with the EMG crossing the threshold turns the stimulator off. The timing circuit disables two consecutive trigger signals in an interval shorter than a preset time; that time is 2 seconds at present.

A custom-designed, two-channel, constant current stimulator, with variable parameters of stimulation within the following limits: I = 0–50 mA, f = 10–50 Hz, T = 10–500 μs was used. The output current can be regulated linearly by changing the value of the electrical resistance connected to the output.

The recordings with the designed device were comparable with recordings obtained using the bench system described previously. The results of each of the phases of processing are presented in **Figure 4** for a single subject, during a session in which the forearm finger flexors and thenar muscle group were stimulated with surface electrodes.

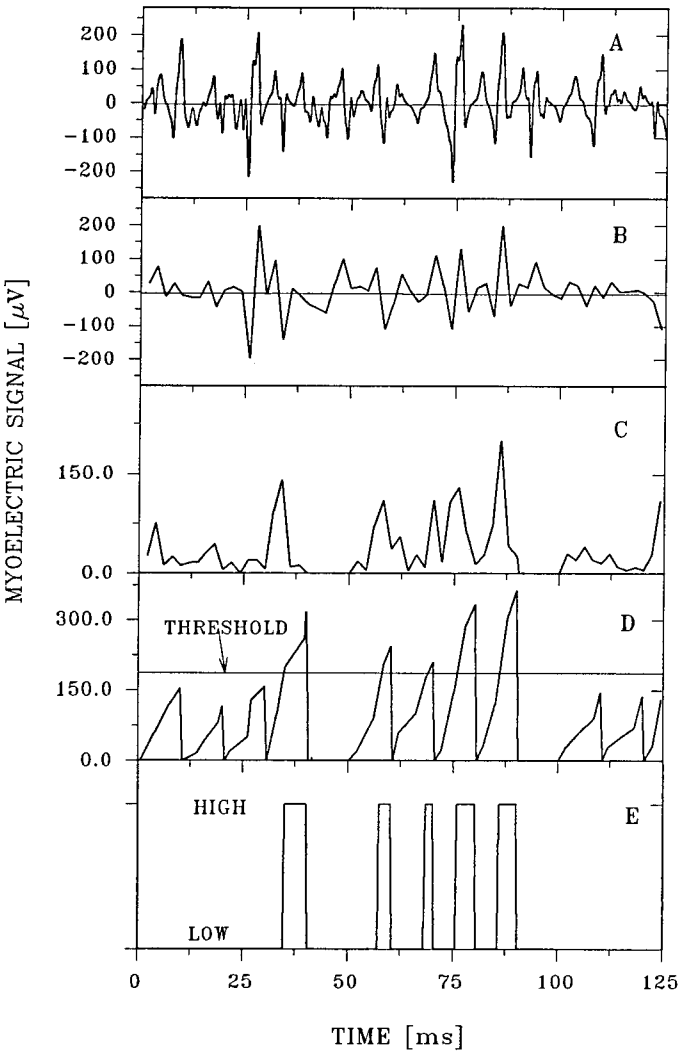

Figure 4.
The signal shape at various stages of the analog processing board. The top trace (A) shows the preamplified signal. This signal is then further amplified and filtered (B), full-wave rectified (C), and integrated with a time constant of 10 ms (D). The peak level that this integrated signal reaches is compared with a fixed predetermined threshold level. The reference level is shown in D. If the integrated EMG exceeds this level, then the output of the comparator is set high (E). Notice that every 50 ms, the rectified EMG is equal to zero for a period of 10 ms (i.e., the blanking circuit grounds the output).

SYNTHESIS OF THE GRASP

Subjects

The same population of subjects participated in this phase of the project, after signing a consent form.

Methods

Using a small probe electrode (1 cm^2) as a cathode, and a large neutral electrode positioned close to the wrist, the motor point of the finger flexors was determined and marked on the skin. Once the position of the stimulating electrodes for each user was determined, the parameters of stimulation were selected to cause a firm grasp without pain or discomfort. It was possible to use very similar parameters of stimulation in all subjects: T = 200 μs, f = 20 Hz, I = 35 mA, monophasic charged compensated pulses. The selective stimulation of finger flexors without activation of wrist flexors was not an easy task when surface electrodes were used. Positioning of the electrodes for the thumb flexors was simple, and small variations in the positions of the electrodes did not play a major role (**Figure 5**).

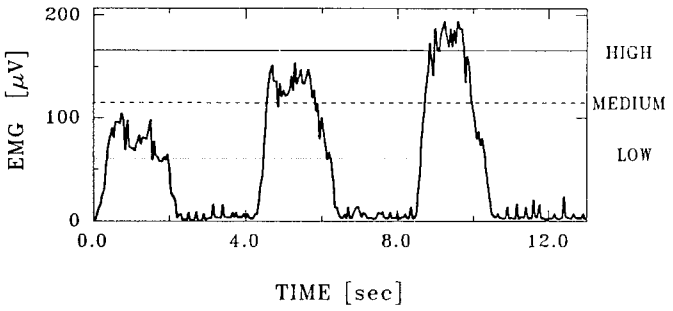

Figure 5.
Multi-threshold control strategy with three levels recorded in a C5 tetraplegic subject. He could control his wrist extension to elicit maximum voluntary contraction or only a fraction of it, but he was not able to maintain the desired level, and he had great difficulties in reproducing the preferred pattern. It was essential to provide him with three-stage feedback (three sounds from the buzzer).

The SCI subjects were trained to experience the stimulation of the finger flexor muscles, while volitionally contracting their wrist extensors simultaneously to generate maximum voluntary contraction. The stimulation was controlled by the physiotherapist. The device was designed with two modes to show when the EMG activity crossed the preset threshold level: an LED and a buzzer. These elements are used as a visual or audio feedback during the training period, as well as for everyday selection of the threshold levels. The SCI subjects were told during the training period to contract their wrist extensors in such a manner as to turn on the LED and buzzer, and to repeat a similar contraction when they wanted to stop the stimulation. Three 30-minute sessions were sufficient to train each of the subjects to control the system with a false triggering rate of less than 0.5 percent.

A potentiometer mounted at the front panel of the device allows the subject to select the threshold on his own, after the positioning of the recording electrodes and a few voluntary contractions of the wrist extensors. The subject adjusts the threshold according to the feedback from the LED or buzzer while volitionally contracting his wrist extensors. The potentiometer is used to adjust the gain of the amplifiers, in case the artifact pickup interferes with the voluntary activation of the device. The adjustment of the gain, if necessary, is done by the subject, when stimulation pulses are delivered, and the recording system is turned on. If the stimulation can turn the system on or off without the contraction of wrist extensors, the gain of the amplifier has to be turned down. It is rarely necessary to change the gain of the device because the artifacts are relatively constant in a given subject. Setting the threshold allows adaptation to effects of impedance changes (drying of electrodes), muscle fatigue, and similar events.

The device has independent control of the stimulation level for each stimulation channel. The subject controls the stimulation delivered to his motor nerves by changing pulse amplitudes. The level of stimulation was selected by the patient when he used video or audio feedback during the stimulation while performing some routine activities. The level of stimulation stayed very much the same, and the adjustments were typically done to reduce effects of muscle fatigue only when the system was used for longer periods. However, once the muscle had fatigued it needed several hours to fully recover, and increased stimulation strength did not improve the grasp.

Results

The subjects were asked to perform a set of typical daily activities selected following the evaluation of the shoulder control in the multichannel implanted functional neuromuscular CWRU stimulation system (3). Ten activities were studied; the final score for each task, both with and without the assistive system was defined from interview data, video recordings done during the sessions, and patient files maintained during the testing (**Table 1**). It was

Table 1.
Activities performed with (Yes) and without (No) the system.

Functional Task	Subject 1			Subject 2			Subject 3			Subject 4			Subject 5			Subject 6		
	No	Yes	Δ	No	Yes	Δ	No	Yes	Δ	No	Yes	Δ	No	Yes	Δ	No	Yes	Δ
Eating With A Fork	1	1+	+	1	1		1	1+	+	0	1	1	1	1+	+	0	1	1
Drinking From Glass	1	1+	+	1	1+	+	1	1+	+	1	1		1	1+	+	1	1+	+
Eating Finger Foods	1	1+	+	1	1+	+	1	1+	+	0	1	1	1	1+	+	1	1+	+
Brushing Teeth	0	1	1	1	1+	+	0	1	1	0	1	1	1	1+	+	0	1	1
Applying Toothpaste	0	1	1	0	1	1	0	1	1	1	1		0	1	1	0	1	1
Using Telephone	0	1	1	1	1+	+	1	1+	+	1	1		1	1		1	1+	+
Handling A Disk	0	1	1	1	1		0	0		0	0		1	1		0	0	
Holding A Book	1	1+	+	1	1		1	1+	+	1	1		1	1		1	1+	+
Writing	1	1+	+	1	1+	+	0	0		0	1	1	1	1+	+	0	0	
Drinking From Mug	1	1		0	0		1	1		1	1		0	0		1	1+	+
TOTAL(S)	6	10	4 (5)	8	9	1 (5)	6	8	2 (5)	5	9	4 (0)	8	9	1 (5)	5	8	3 (5)

Δ = difference in performance by using system; numbers in parentheses = functions where noticeable improvement was seen; numbers without parentheses = functions performed with the system only; 1 = success; 0 = failure; + = noticeable improvement

found that grasping was improved for most of the activities; hence, this device improved the quality of daily living in a selected group of subjects with tetraplegia. The performance of each activity was scored only as **success** marked "1," **failure** marked "0," and **noticeable improvement** marked "+."

Noticeable improvement was given as a grade in the following cases: 1) firmer and stronger grip when manipulating objects (pronation, supination, elbow flexion and extension); 2) enabling the prolonged holding pattern for at least 30 percent compared with no system; and, 3) shortening the time needed to grasp the object by at least 30 percent compared to tenodesis only. The maximum score for each individual subject was 10; hence, the total score for the 6 patients is between 0 and 60. The total score for all study subjects tested without the device was $S = 38$ ($S_{mean} = 6.33$, $\sigma = 1.36$), compared to the score when using the FES system $S = 53$ ($S_{mean} = 8.62$, $\sigma = 0.75$). This score does not include the noticeable improvement in performance. Improvement in grasping function ("+" signs, **Table 1**) was noticed in 25 of 38 function tests (65.68 percent).

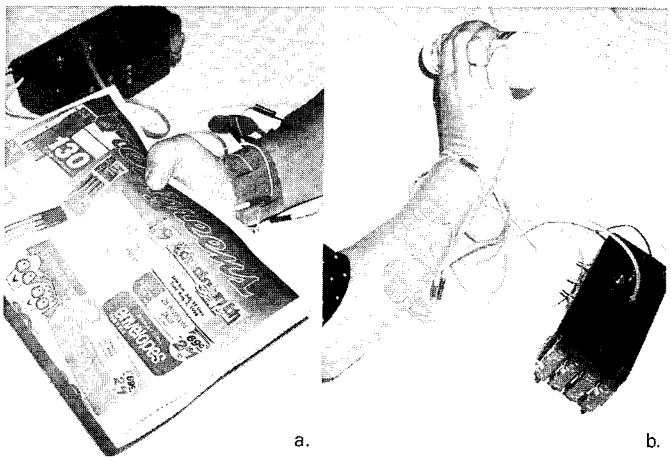

Figure 6.
A forearm of a subject instrumented with the EMG controlled tenodesis enhancement orthosis while holding the newspaper (left), and the little bottle (right). Note neutral and thumb electrodes for stimulation (left), and EMG recording electrodes (right).

DISCUSSION

The designed device works using an on-off controller, and there is no gradation in the force. The use of disposable polymer electrodes that can stay on the skin for several days is very effective, and no side effects have been noticed so far (23). Donning of the system requires minimal help of a somewhat trained person to connect the electrodes to the stimulator and position recording and stimulating electrodes on the forearm. The subject, if necessary, can set the threshold and the gain to suitable levels by using the LED or buzzer feedback.

Prolonged clinical and home use of the device showed that there are no side effects and that SCI subjects may want to use such a system on a daily basis.

It was feasible to grade the strength of the stimulation using the recordings (**Figure 6**) and multi-threshold triggering; hence, the performance can be improved. However, subjects who participated in our study seemed to prefer the single threshold device, because of the simplicity of the application.

It was possible to stimulate motor nerves with variable pulse width using a multi-threshold control strategy, but it required fine tuning of the gain of the device and thresholds. Experiments with this technique are not practical at this point, because the subjects had great difficulty selecting the appropriate EMG level and maintaining it when pronating and supinating.

The device presented has a hardware processing circuit suitable to be incorporated in a micro-computer system. A programmable micro-controller can easily integrate the self-tuning of the sensory part of the system based on initial recordings of the EMG when the wrist is relaxed and when an MVC is generated. In our recent design, with one threshold, it was possible to avoid daily fitting and to use the device for several days on the same subject without any tuning. Adjustment of the threshold of the comparator and the gain of the amplifier was necessary from subject to subject.

The hardware can be replaced with a fully implanted system, and many of the problems (selectivity of stimulation, decreased power consumption, stimulation of several motor nerves to allow controlled thumb flexion and extension in addition to finger flexion, and ease of daily donning and doffing) will be resolved (24).

CONCLUSIONS

The general conclusions are: 1) the system increases the strength of the tenodesis grasp; 2) training period for the use of the system lasts about 30 minutes per session; 3) side effects and related problems were not noticed; and, 4) reliability of the operation is good. Functional tests of the system showed that some subjects do not benefit from this approach, because of the disuse and denervation types

of muscle atrophy of their finger flexors, the lack of controllable wrist extension, the curled resting position of IP joints, and the inability to bring the thumb into opposition.

Another approach to enhance grasping is to use a mechanical brace, but this was intentionally omitted as our approach was to develop a functional device to maximize preserved functions, and eliminate any complicated, custom-fitted, hardware. In addition, the device is: 1) minimally invasive, 2) mounted on one forearm, 3) voluntarily controlled by the same arm, 4) applicable for individuals who are not benefiting from the fully implantable multichannel FES system sufficiently to be encouraged to undergo the implantation, and 5) easy to maintain and apply on a daily basis.

This paper described the feasibility study; hence, a clinical evaluation and comparison with other assistive systems are needed to confirm its performance. The myoelectric tenodesis enhancement device was given to three of the six subjects who participated in the study, for their daily use.

ACKNOWLEDGMENTS

This paper is dedicated to Mr. Dean Charles, whose ideas and excellent research developments and designs contributed to better understanding of motor control in humans and animals. We would like to acknowledge the suggestions and the important contribution to this control method by Dr. Richard B. Stein, University of Alberta, Edmonton, Alberta, and the excellent technical support of Mr. Zoran Nikolić, doctoral student at the Department of Biomedical Engineering, University of Miami.

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Gait parameters following stroke: A practical assessment

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Abstract—Mechanical methods of quantifying gait are more sensitive to change than is direct clinical inspection. To assess gait parameters and patterns of patients with stroke, and the temporal changes of these parameters, a foot-switch gait analyzer was used to test 49 ambulatory patients with stroke and 24 controls. Patients walked significantly slower than controls, with decreased cadence, increased gait cycle, and increased time in double limb support. Patients' hemiplegic limbs spent more time in swing and stance when compared to controls; their unaffected limbs spent significantly more time in stance and single limb support compared to controls. Patients' hemiplegic side, when compared with the unaffected side, spent less time in stance and more time in swing. A flatfoot pattern was typically noted on the affected side. General gait parameters improved over time, with the largest changes occurring in the first 12 months. However, the percentage of time spent in double and single limb support, stance and swing, parameters which describe the asymmetrical pattern of gait, did not change over time. Abnormal gait was due to difficulty in moving the body over an unstable limb. Gait analysis can be of importance in documenting abnormalities and determining the effects of therapeutic modalities.

Key words: *functional recovery, gait, gait analysis, hemiplegia, rehabilitation, stroke, walking cycle.*

INTRODUCTION

Ambulation is a significant part of the functional recovery following stroke and depends on several factors, including size and location of the infarct (1) and premorbid health. Quantitated gait analysis may be useful in monitoring gait performance and functional recovery following stroke (2–6); however, gait patterns are quite variable (1,4,6). Such variability has been described for velocity, cadence, stride length, and patterns of asymmetry (5,7,8), even in a clinically homogeneous group (6). It has been recognized that certain gait parameters following a stroke will mirror a patient's overall functional recovery. Patients who survive strokes have shown improvement in gait velocity, cadence, stride length, step length, stride time, single limb support, and stance over time (5,9–12), with most improvement occurring in the first 3 months following the stroke (5,10). Our purpose was to quantify and describe the gait of patients with stroke, using a practical gait analyzer and assess the temporal changes of these parameters.

SUBJECTS AND METHODS

Forty-nine patients with stroke were assessed and compared with 24 age-matched controls. The patients were all functionally ambulant, had a mean age of 64.2 years and were on average 43.4 months post-stroke (range 0.5–336 months). Of the 49 patients, 9 had no hemiplegia and 2 had bilateral symptoms; these 11 patients were therefore analyzed separately. Of the 38 hemiplegic patients, 10 were assessed at two different times during their rehabilitation: these were treated as independent observations for a total of 48 assessments (**Table 1**). Control patients had either transient ischemic episodes (TIA) or asymptomatic carotid stenosis and had normal physical examinations and symmetrical gait without the use of walking aids. All patients

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Table 1.
Patient Characteristics.

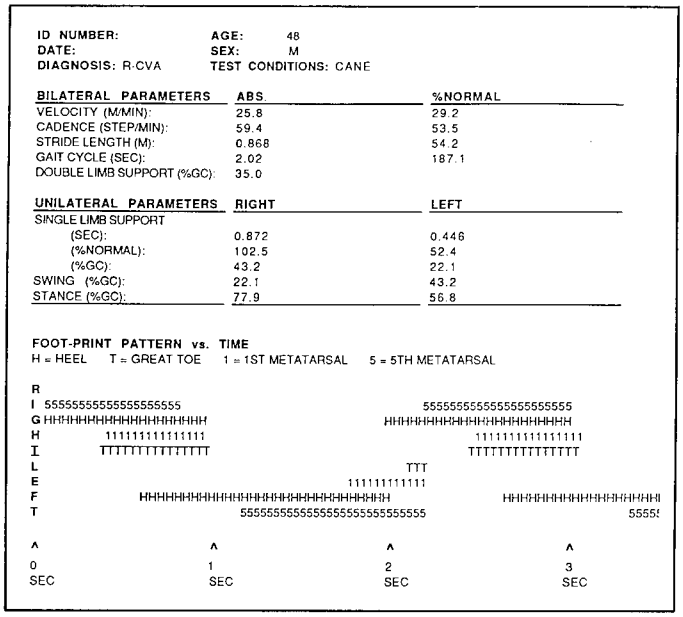
	All Stroke Patients	Hemiplegic Patients	No Symptoms	Bilateral Symptoms	Control
Number	59	48	9	2	24
Male (%)	90	90	89	100	88
Female (%)	10	10	11	0	13
Age	64 ± 10	65 ± 10	61 ± 15	59 ± 4	64 ± 10
	[30–82]	[4–82]	[30–73]	[24–79]	[24–79]
Months since stroke	43 ± 70	46 ± 77	33 ± 28	26 ± 15	—
	[0.5–336]	[0.5–336]	[2–72]	[15–36]	
Assessment:					
0–3 mos	14	13	1	0	—
> 3–12 mos	10	7	3	0	—
> 12–36 mos	11	7	2	2	—
> 36 mos	24	21	3	0	—
Assist/Orthoses	19	19	0	0	0
cane	12	—	—	—	—
ankle/foot orthosis	7	—	—	—	—
walker	2	—	—	—	—
assistant	2	—	—	—	—
rail	1	—	—	—	—
Side					
right	34	34	—	—	—
left	14	14	—	—	—
bilat	2	—	—	2	—
neither	9	—	9	—	—

Mean ± 1 SD, [range].

and control subjects were free of any other medical problems which interfered with gait.

Gait was analyzed using a portable stride analyzer (B & L Engineering, Santa Fe Springs, CA). The device consisted of insoles which contained four compression-closing foot switches in the heel, first and fifth metatarsal, and great toe regions. When placed in the subject's shoes, the insoles were connected to a lightweight mobile data collection box worn on a belt. Subjects walked on an 18-meter thinly carpeted hallway, and data were collected over the middle 6 meters, delineated by photoelectric cells. The data were transferred to a personal computer for analysis of comprehensive and unilateral gait parameters. Comprehensive parameters were measurements determined from both legs; these included gait velocity (meters/sec), cadence (steps/min), stride length (distance from heel strike to heel strike of the same leg, in meters), gait cycle (time in seconds from heel strike to heel strike of the same leg), and total double limb support (duration of time that both limbs were on the ground per cycle, in seconds and as a percentage of gait cycle). Unilateral parameters which were determined for each limb individually, included: single limb support (duration of time one leg was on the ground by itself, in seconds and as a percentage of gait cycle), duration of swing phase (time a single limb was not on the ground, in seconds and as a percentage of gait cycle), and stance phase (total time single limb was on the ground, in seconds and as a percentage of gait cycle). A typical gait printout illustrating the gait parameters and footprint pattern is shown in **Figure 1.** Footprint patterns displayed the relative amount of time spent on four regions of the foot. Gait parameters were compared between patients with stroke and controls using an unpaired two-tailed Student's t-test (significance at $\alpha < 0.05$).

Patients were divided into four subgroups based on time from stroke: (a) less than 3 months post-stroke, (b) 3 to 12 months, (c) 12 to 36 months, and (d) greater than 36 months post-stroke. To test reproducibility of the gait



ID NUMBER: AGE: 48
DATE: SEX: M
DIAGNOSIS: R-CVA TEST CONDITIONS: CANE

BILATERAL PARAMETERS	ABS.	%NORMAL
VELOCITY (M/MIN):	25.8	29.2
CADENCE (STEP/MIN):	59.4	53.5
STRIDE LENGTH (M):	0.868	54.2
GAIT CYCLE (SEC):	2.02	187.1
DOUBLE LIMB SUPPORT (%GC):	35.0	

UNILATERAL PARAMETERS	RIGHT	LEFT
SINGLE LIMB SUPPORT		
(SEC):	0.872	0.446
(%NORMAL):	102.5	52.4
(%GC):	43.2	22.1
SWING (%GC):	22.1	43.2
STANCE (%GC):	77.9	56.8

FOOT-PRINT PATTERN vs. TIME
H = HEEL T = GREAT TOE 1 = 1ST METATARSAL 5 = 5TH METATARSAL

R
I 55555555555555555555 5555555555555555555555
G HHHHHHHHHHHHHHHHHHHH HHHHHHHHHHHHHHHHHHHHHH
H 1111111111111 1111111111111
I TTTTTTTTTTTTTT TTTTTTTTTTTTTT
L TTT
E 111111111111
F HHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHH HHHHHHHHHHHHHHHHHHHH
T 555555555555555555555555555 55555

^ ^ ^ ^
0 1 2 3
SEC SEC SEC SEC

Figure 1.
Sample gait analysis printout illustrating gait parameters and footprint pattern. This stroke patient had a typical gait pattern characterized by decreased velocity, cadence, and stride length. The patient's weaker left leg spent less time in single limb support and more time in stance. The converse was true for his normal right leg. The footprint pattern shows an abnormality of the left foot with the heel and fifth metatarsal regions striking the ground at the same time and lifting of the entire foot at once instead of a normal progression from the back to the front of the foot. The right footprint is normal in appearance except that it is elongated due to an increased amount of time spent on this normal side.

analyzer, two control subjects and five patients with stroke each walked twice in sequence. The pair of analyses for each patient were then compared.

RESULTS

The age of patients with stroke was comparable to the control group ($p = 0.97$). In two patients, gait was characterized by dragging both feet and hence only velocity could be determined over the length of the walk. The comprehensive gait parameters of all other patients ($n = 57$) were compared to the control group and are summarized in **Table 2.** Hemiplegic patients walked significantly slower than controls ($p < 0.0001$), with decreased cadence ($p < 0.005$), increased gait cycle ($p = 0.02$), and a slightly shorter stride ($p = 0.07$); however, the stride length did not reach statistical significance when compared to controls. Of interest was the finding that stride length was linearly proportional to cadence ($p = 0.04$).

Patients with no hemiplegia or bilateral symptoms had parameters which were similar to control subjects. The two patients with bilateral symptoms had relatively normal gait on clinical inspection.

Patients with stroke tended to spend more time in double limb support than controls when measured in real time, presumably because this was a more stable arrangement. However, as a percentage of gait cycle, both patients and controls spent roughly an equivalent amount of time in double limb support (**Table 2**).

The unilateral measurements (**Table 3**) were assessed only for the patients who had a documented history of hemiplegia at the time of their stroke ($n = 48$). Data from control patients' right and left legs were compared and showed no significant differences, hence all unilateral data were pooled in this group ($n = 48$). As a group, the patients with a history of hemiplegia had a typical gait pattern (**Figure 1**). Their affected limbs spent more time in swing phase, significantly more time in stance phase ($p = 0.03$), and approximately an equivalent time in single limb support when compared to controls. However, when calculated as a percentage of gait cycle, which was longer in the patients with stroke, these patients spent a relatively similar amount of time in swing and stance phases and less time in single limb support on the affected side compared to controls (**Table 3**).

Patients' unaffected limbs spent significantly more time in stance phase ($p = 0.01$) and single limb support ($p = 0.04$) and approximately an equivalent time in swing phase compared to controls. As a percentage of gait cycle, patients spent relatively less time in swing phase, more time in stance phase, and an equivalent time in single limb support on their unaffected side compared to controls (**Table 3**).

Patients' affected side, compared to the unaffected side, showed that they spent less time in single limb support and stance and more time in swing with their affected side. Conversely, they spent more time in stance and less time in swing on their more stable unaffected side. This pattern was evident in the majority of patients; only three spent more time on the leg of the affected side. These three patients, who were 3 to 4 years post onset, all reported no weakness in either leg, although two of them showed mild weakness (graded 4 out of 5) of the leg of the affected side on physical examination.

Footprint patterns illustrated that the patients typically had a normal but elongated footprint on the unaffected side due to the increased time spent on this limb. A flatfoot pattern was typically noted on the affected side in

Table 2.
Gait parameters of patients with stroke and control subjects.

	All Patients	Hemiplegic Patients	No Symptoms	Bilateral Symptoms	Control
Velocity (m/min)	48.3 ± 22.7*	44.0 ± 22.9*	68.5 ± 6.7	58.6 ± 10.8	64.0 ± 10.4
Cadence (stps/min)	88.3 ± 21.5	84.8 ± 22.4*	102.8 ± 5.0	104.5 ± 7.1	95.0 ± 12.5
Stride length (m)	1.1 ± 0.6	1.1 ± 0.6	1.3 ± 0.1	1.1 ± 0.1	1.3 ± 0.5
Gait cycle/sec	1.5 ± 0.6	1.6 ± 0.7*	1.2 ± 0.1	1.2 ± 0.1	1.2 ± 0.3
Double support:					
% gait cycle	—	37.4 ± 10.9	—	—	35.1 ± 6.2
seconds	—	0.62 ± 0.46	—	—	0.43 ± 0.09

*$p < 0.05$; mean ± 1 SD.

Table 3.
Unilateral gait parameters, as percentage of gait cycle.

Parameter	Hemiplegic Patients with Stroke		Control R and L:
	Affected side:	Unaffected side:	
SLS (%GC)	29.2 ± 8.6	33.0 ± 6.6	32.4 ± 3.4
(sec)	0.43 ± 0.19	0.51 ± 0.23	0.40 ± 0.12
Swing (%GC)	33.0 ± 6.6	29.2 ± 8.6	32.4 ± 3.7
(sec)	0.51 ± 0.23	0.43 ± 0.19	0.40 ± 0.12
Stance (%GC)	67.0 ± 6.6	70.8 ± 8.6	67.6 ± 3.7
(sec)	1.06 ± 0.50	1.14 ± 0.60	0.83 ± 0.20

Mean ± 1 SD; SLS = single limb support; GC = gait cycle.

which the heel and metatarsal regions made contact with the ground at a similar time. Furthermore, they had decreased toe contact on the affected side, and a pattern in which the great toe struck the ground first was observed in one case. Variability of footprints was noted, particularly on the patients' affected side, and a variability of subsequent stance and swing phases was also frequently observed due to small variations in the duration patients spent on the affected and unaffected legs.

The analysis of patient data with respect to time from stroke for each patient, revealed that parameters improved with increasing time post onset. This indicated that there was improvement in all parameters over time, with the largest changes occurring in the first 3 months for velocity and in the first 12 months for the other parameters. **Figure 2** illustrates the increase of cadence with time. This increase was inversely proportional to the duration of the gait cycle which decreased with time. Stride length and velocity also improved with time and were proportional to each other.

In contrast, double limb support and single limb support, stance and swing as a percentage of gait cycle for both affected and unaffected sides did not change appreciably over time (**Figures 3** and **4**). The general pattern in which patients spent more time weightbearing on the unaffected side and more time in swing with the affected side was consistent.

As a test of reproducibility, seven patients walked a total of 16 times in sequence. Unilateral parameters changed an average of 7.4 percent, comprehensive parameters changed an average of 20.7 percent. The relatively large changes of comprehensive parameters were observed to be due to patient variability in subsequent swing and stance phases as determined by inspection of the footprint patterns, and not due to measurement inaccuracy.

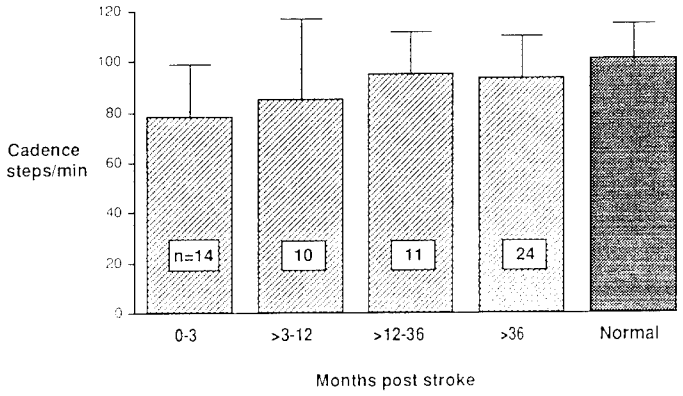


Figure 2.
Temporal changes of cadence with time since stroke. Error bars represent standard deviation.

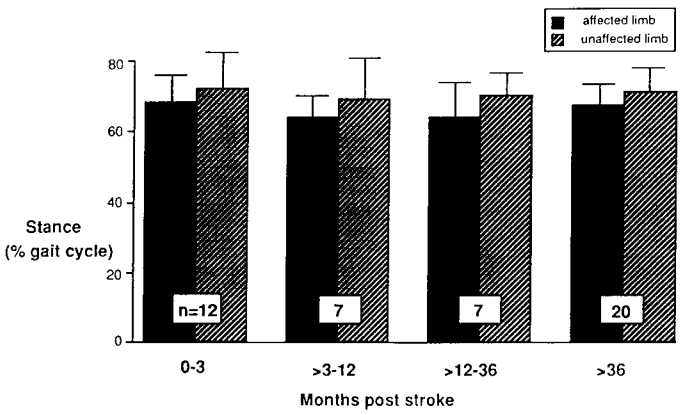


Figure 3.
Stance phase of gait vs. time since stroke. Patients spent less time on the affected leg and more time on the unaffected leg. This abnormal pattern remained constant with time. Error bars represent standard deviation.

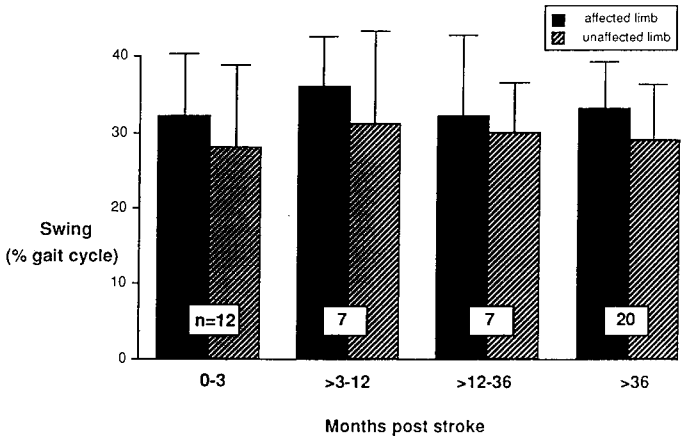


Figure 4.
Swing phase of gait vs. time since stroke. Patients' affected legs spent more time in swing, whereas the unaffected legs spent less time in swing. This abnormal pattern remained constant with time. Error bars represent standard deviation.

It is important to note that the age-matched control patients analyzed in this study had abnormal gait parameters. When compared to 500 nondisabled subjects, our control patients walked slightly slower and with decreased stride length (both 82 percent of normal), and decreased single stance (78 percent of normal). Their cadence (95 percent of normal), and gait cycle (108 percent of normal) were within the normal range.

DISCUSSION

Compared to age-matched control patients and nondisabled subjects, patients with stroke have decreased walking velocity, cadence, and stride length, and an increased gait cycle. These results are in agreement with the observations of others (8,13,14) and variations in the magnitude of these parameters are due to the wide variability of gait after stroke (1,4,6,15) as reflected by the high standard deviations of the gait parameters. Variability may also be due to the relative higher function of subjects in our group, the longer time period since stroke, and complete recovery in many of our patients. Decreased velocity, cadence and stride length are a compensation for poorer motor control (8).

The age-matched control patients in our study showed gait parameters which deviated from normal despite normal physical examinations, normal motor power, normal balance, and symmetrical gait. These deviations were likely due to the advanced age of this group: only four patients were under the age of 60, but any effects of their vascular pathology cannot be strictly ruled out. Although the use of this control group results in decreased significance of the abnormalities seen in our patients with stroke, we feel these two age-matched groups provide a more realistic comparison and provide results of greater clinical significance.

Asymmetry, which has also been correlated with motor recovery (7), was one of the most obvious features of the abnormal gait of patients with stroke. A lack of smoothness in forward progression, inequality in subsequent stance phases, swing phases, and step lengths were also observed. The variability of all these parameters was likely due to balance deficiencies and difficulty in moving the body over an unstable limb. More time was spent in stance on the unaffected side than on the paretic side. During the relatively briefer amount of time the patients' weight was over the paretic limb, the unaffected limb was quickly advanced to the next floor contact resulting in a shorter swing phase for the unaffected limb. Conversely, with an increased stance on the unaffected limb, the paretic limb spent more time in swing. Of importance was our observation that the relative duration of swing and stance phases with affected and unaffected limbs remained constant after stroke, despite improvement of other parameters. Compared to controls, patients with stroke had a longer single stance with both affected and unaffected legs independently as well as during double limb support.

General gait patterns which have been observed in patients with stroke include: a toe-first or entire sole down during stance and toe drag or inversion of the foot during swing (5,16). Foot drag may trigger pressure mats or foot

switches and must therefore be distinguished from support time (5). For this reason, footprint patterns must be examined: this led to the rejection of two patients in our study who made significant floor contact by dragging their feet, giving inaccurate gait parameters. The toe-first pattern was seen in only one stroke patient in our study; most patients walked with a relatively flat foot on the affected side, but with decreased toe contact. It is likely that other patterns were not seen due to the high function of the outpatients tested in this study. Nevertheless, of significant note was that the gait analyzer clearly showed minor abnormalities which were not noted by clinical observation of the patients during their test walk. This may be of diagnostic significance and may be useful for following rehabilitation.

Walking speed has been observed to improve over the first 3 months after a stroke (12) with minimal consistent improvement or constant disability thereafter (17). It has also been reported that the longer a patient took to start walking, the less he or she was able to regain normal gait performance (12). Conversely, better early function has been correlated to further improvement or maintaining gait performance at one year (11) with recovery proportional to stroke severity, not age or sex (18). Nevertheless, despite these observations, patients may also worsen over time (11) due to changes in the paretic limb and underlying medical conditions. Velocity, the product of stride length and cadence, improved over time due to a proportional improvement of both stride length and cadence which were linearly correlated to each other. Despite the considerable improvement of these three general parameters as well as the duration of the gait cycle, the typical gait pattern with the affected side spending more time in swing and the contralateral side spending more time in stance, remained consistent and did not improve over time. This observation may indicate that patients compensate for their abnormal pattern with improved confidence, training or balance; thus resulting in improvement of the general parameters such as velocity, cadence, and stride length which are less dependent on gait pattern. We propose that recognition of this constant pattern may be useful in assessing the effects of therapeutic modalities following stroke. With the knowledge of a constant ratio of the swing and stance phases of the affected to unaffected sides, observation of an improvement of this ratio may be of major significance.

Of all patients assessed, only three spent more time on their affected side. These patients did not perceive a unilateral weakness, although weakness was noted on physical examination in two of them. This is unlikely to be due to an overcompensation for their weakness, but rather an inability of the weak leg to perform at normal velocity and stride length. Although the other patients in this study did not have demonstrable weakness of their unaffected side, it must be kept in mind that stroke may affect both sides, and the relatively stronger side may compensate for the contralateral more affected side.

Variations of gait, particularly with respect to asymmetry, suggest that it is not possible to design a single gait reeducation program for all patients and that unique deficiencies of each patient must therefore be addressed (6). For this reason, gait analysis is indicated to determine deficiencies, guide therapy, and monitor progress. Gait laboratories yield information which is comprehensive, but often difficult to correlate clinically, hence decreasing their practical application. As a consequence, ambulation is often clinically assessed as: absent, abnormal with or without assistance, or normal. The gait analysis system used in this study proved to be simple to operate and interpret, and capable of detecting small changes with time. We propose that it is an ideal screening method for gait abnormalities and useful for following patient progress. The wide range of parameters within our control group may be due to the fact that they were not entirely normal, and included patients with TIAs and asymptomatic carotid stenosis. It is interesting to speculate that quantitative gait analysis may be more sensitive in detecting subtle abnormalities which cannot be seen on computed tomography, physical, or neurological examinations. This potential sensitivity of gait analysis is of importance and requires further exploration.

This study represents the first application of a simplified gait analysis system to quantify gait parameters and the temporal changes following stroke in a large number of patients. Gait analysis in general can be of significant importance in determining and following the results of surgical and other therapeutic modalities for the documentation, correction, and improvement of abnormal gait patterns. Ambulation is of obvious importance in the physical and mental state of the stroke patient and we propose that the application of simplified gait analysis as a tool for assessing patients with stroke will aid in diagnosing and following gait aberrations and the effects of therapeutic modalities.

CONCLUSIONS

The gait analyzer provided relevant statistical data, and allows for simple follow-up post-stroke. It was reliable and easy to use and inexpensive compared to a gait labo-

ratory. The gait of patients with stroke was characterized by decreased velocity and cadence, and increased gait cycle and double limb support. Their affected limbs spent more time in swing and stance, and their unaffected limbs spent more time in stance and single limb support compared to controls. The patients' hemiplegic side, when compared with their contralateral side, spent less time in stance and more time in swing. A flatfoot pattern was typically noted on the affected side. General gait parameters improved over time, with the largest changes occurring in the first 12 months; however, parameters which describe the asymmetrical pattern of gait did not change over time. These included the percentage of time spent in double and single limb support, stance, and swing. The abnormal gait was probably due to difficulty in moving the body over an unstable limb. The ability of the device to demonstrate abnormalities which were not evident on clinical evaluation is a potentially important observation.

ACKNOWLEDGMENTS

This project, as well as countless others, pays tribute to the inspiration of Dr. Vernon Nickel who passed away prior to completion of this paper.

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Establishment of consistent gait after fitting of new components

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Abstract—Since the time required for a person with an amputation to become familiarized with a prosthesis after a change of a component is not known, the gait of a single subject, a man with a through-knee amputation, was examined with two different knee mechanisms interchanged in the same prosthesis. Several parameters were analyzed to determine when the subject's gait had stabilized sufficiently to permit confident assessment of the appropriateness of the knee mechanisms. At least one week of functional walking was required before a clinical decision could be made about the suitability of the component. For the purposes of research, it was deemed preferable to try knee mechanisms for at least 3 weeks to be sure pertinent gait parameters stabilized.

Key words: *amputees, artificial limb, biomechanics, gait, knee joint, prosthesis design.*

INTRODUCTION

In both the clinical setting and the research environment, prosthetists make assumptions about gait quality outcomes after prosthetic components have been fitted or alignment has been altered. Often, these judgments are made after only brief practice sessions by the person being tested. The subjective nature of these assessments, or the assumptions on which later measures are based, are questionable. This is due, in part, to the unacceptably low sensitivity of visual observation (mean sensitivity = 22.2 percent) as reported by Saleh and Murdoch in 1985 (1); to the broad range of alignments and components tolerated by many people with amputations (2); and to the fact that some measures, such as pressures and torques, are not readily observable.

This study posed the question: if different components are to be compared to ensure optimal gait outcomes, when can the prosthetist be confident that gait performance is stable and, thus, make the decision to accept or reject a component?

METHOD

A single case study with repeated measures was used to investigate this question. The subject was an active 26-year-old man who had a through-knee amputation as a result of a motor vehicle accident 9 years prior to the study. He leads an active life as the father of two small children and in his employment in fitting and maintaining domestic and industrial appliances. The subject used a Teh Lin® pneumatic knee mechanism in his prosthesis for 3 years. Prior to that he had always been fitted with an Otto Bock® 3R21 knee mechanism. The test prosthesis was fabricated to resemble the subject's usual limb as closely as possible while allowing easy knee unit substitution.

Two test knee units were used in the prosthesis. The first was an Otto Bock® 3R46, a polycentric unit with hydraulic swing control, and the second was a 3R30, a similar Otto Bock® unit with friction swing control.

The subject wore the test prosthesis with the hydraulic knee in place for 4 weeks. Sagittal and posterior data collections were taken immediately after fitting and then each week for the next 3 weeks, at the same time of day and week as the initial collections. The friction controlled

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knee unit was then fitted, replacing the hydraulic unit, and the process repeated. The manufacturer's recommendations for correct knee unit alignment were followed and no other components altered.

After the initial test period on each knee mechanism, the subject chose to continue wearing the prosthesis with the friction knee as his regular limb, making it possible to take a further series of five data collections at weekly intervals commencing 13 weeks later.

Data were collected using a Selspot® Movement Monitoring System linked with an AMTI® force platform; the subject traversing the walkway at his preferred walking speed. A total of 325 data collections were taken and calculation of the joint forces, moments, and powers were made using a link segment model (3).

Data from five walks taken on each collection day were averaged and the coefficient of variation (CV) calculated for each of the measured parameters.

Thirteen trials were available for comparison, grouped into three conditions:

1. hydraulic knee trials taken Weeks 0 to 3 (condition 1)
2. friction knee trials taken Weeks 4 to 7 (condition 2a)
3. friction knee trials taken on Weeks 21 to 25 (condition 2b).

Differences both within and between conditions were examined. Key parameters selected for closer examination, including CV, were:

- vertical ground reaction force
- step and stride kinematics
- preferred walking speed
- vertical heel rise
- knee angular velocity
- time taken to reach peak vertical force.

Statistical Analysis

Because the data to be analyzed were time series, the coefficient of variation (CV) is used to demonstrate the variability of the signal from the mean. The CV was calculated according to Winter (4) and expressed as a percentage:

$$CV = \frac{\sqrt{1/N \, \Sigma \, \sigma_i^2}}{1/N \, \Sigma |X_i|} \times 100$$

WHERE N = number of intervals over the period
X = mean value of variable at *i*th interval
σ_i = standard deviation of variable X about X_i

RESULTS

Both within and between conditions there was no significant difference in preferred walking speed (mean for condition 1 = 1.47 ms^{-1}; condition 2a = 1.45 ms^{-1}; condition 2b = 1.47 ms^{-1}), and the vertical ground reaction force showed low variability (CV = 7–12 percent).

For condition 1 the analysis revealed a reduced stance time in the last trial (**Figure 1**). This reduced stance time remained for the first trial in condition 2a, but stance time increased for the following two trials. The final trial in this condition showed stance time had reverted to first trial duration (**Figure 2**).

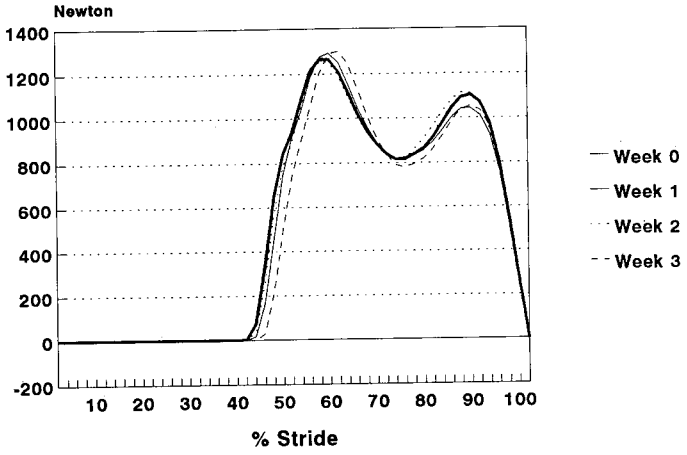

Figure 1.
Vertical ground reaction force, condition 1: hydraulic knee.

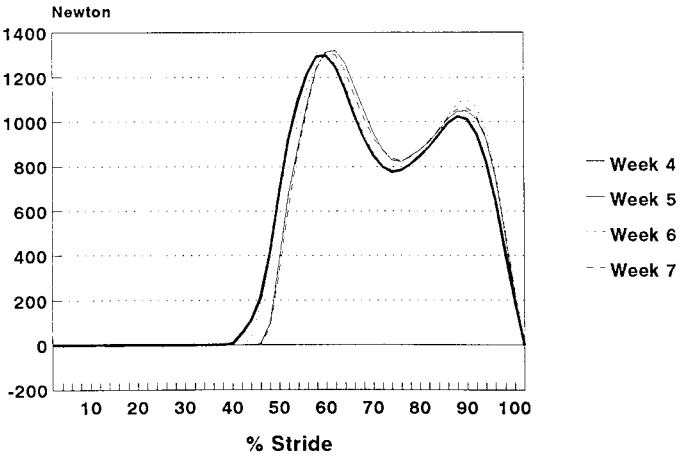

Figure 2.
Vertical ground reaction force, condition 2a: friction knee.

Stance phase duration for condition 2b (**Figure 3**) was consistently at the lower range.

In the graph of the knee angular velocity for condition 1 (**Figure 4**), an established pattern across all trials can be seen. The graph shows similar peaks and a negative velocity prior to toe-off. For condition 2a (**Figure 5**), the pattern is similar to condition 1 immediately after fitting the friction knee mechanism, but changes to a different 'standard' pattern for this knee over time.

When condition 1 was compared with condition 2a the following changes were noted:

- the time taken to peak load (T_1, **Figure 6**) was shorter

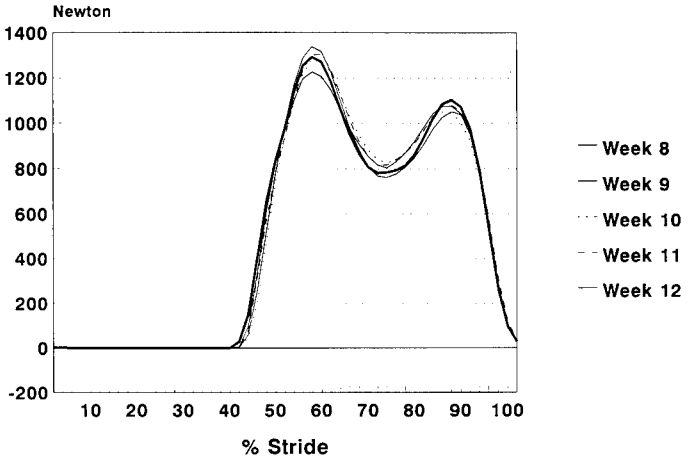

Figure 3.
Vertical ground reaction force, condition 2b: friction knee.

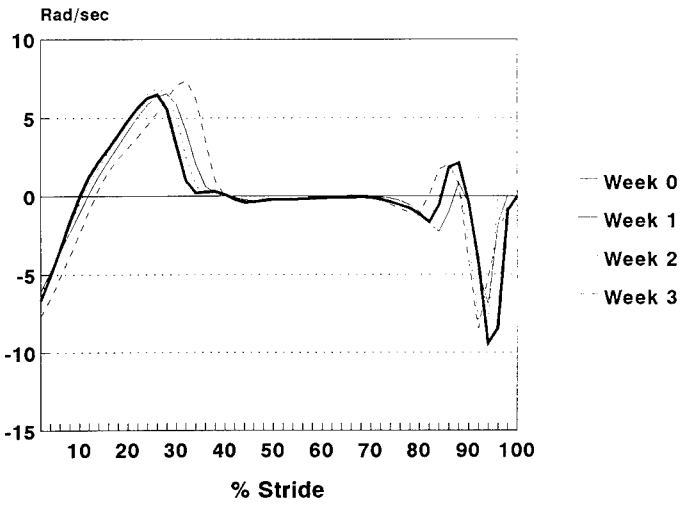

Figure 4.
Knee angular velocity, condition 1: hydraulic knee.

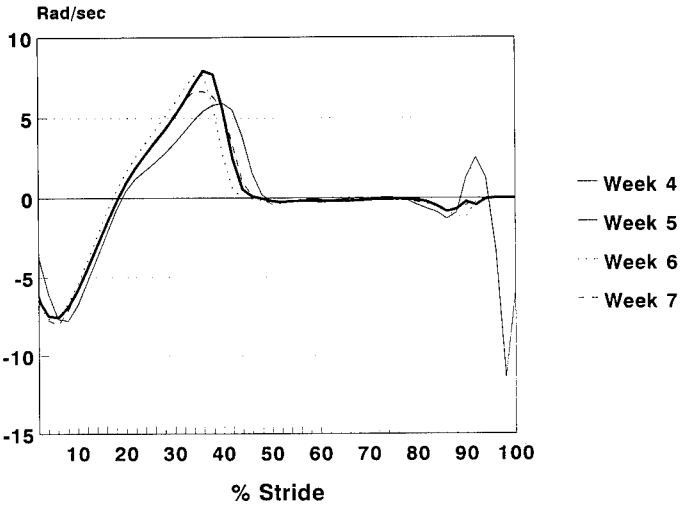

Figure 5.
Knee angular velocity, condition 2a: friction knee.

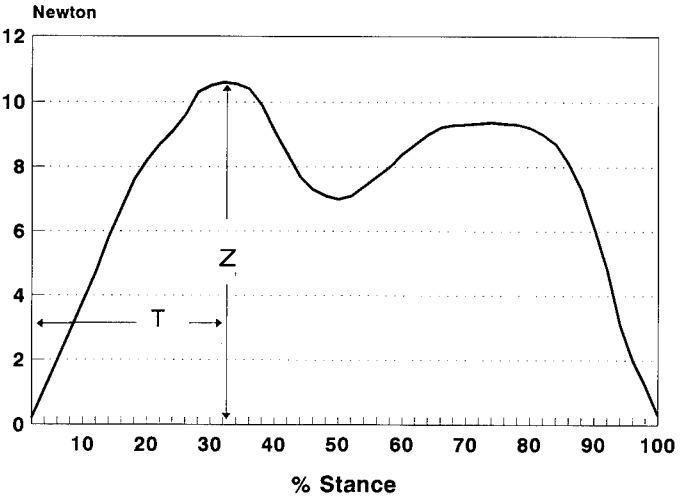

Figure 6.
T_1: time taken to reach first peak vertical ground reaction force.

- the vertical ground reaction force had a lower CV, although both were near the normal limits of 10 percent (4)
- the knee angular velocity had a lower CV
- the hip moment recorded for had a lower CV.

Only the hip power displayed a higher CV for condition 1.

When comparing condition 2a with condition 2b, the following values reduced:

- the average T_1 (condition 2a = 61 percent stride, condition 2b = 58 percent stride)

- the knee angular velocity CV (condition 2a = 55 percent, condition 2b = 26 percent)
- the knee angle CV (condition 2a = 17 percent, condition 2b = 15 percent)
- the CV of the vertical ground reaction force (condition 2a = 12 percent, condition 2b = 7 percent).

DISCUSSION

Figures 4 and **5** indicate a 'settling in period' where Week 1 data differ noticeably from Weeks 2 to 4 on the second test knee mechanism. It can be presumed, therefore, that the subject needed to wear the altered prosthesis for at least one week before a decision about the effectiveness of the change could be supported. This time is needed to allow for adapting to the new component by modifying a practiced gait pattern. The increased stance phase duration recorded in the middle two trials of condition 2a further indicates that maximal gait quality measurement requires at least 3 weeks of practice before gait stability can be assumed.

While clinical decisions may be made after one week it is suggested that, for purposes of research, an altered limb should be worn for at least 3 weeks to ensure that consistent walking performance is be obtained.

The reduction in variability of the vertical ground reaction force from 12 percent to 7 percent (**Figures 2** and **3**) between condition 2a and condition 2b indicates improvement in walking consistency over the 21 weeks, but it is not suggested that this extended time is necessary before decisions can be made about gait stability.

The accepted global measure of gait quality (5), walking speed, was not sensitive enough to reveal the inconsistency brought about by the changing of the knee unit. This indicates that this measure cannot be used in a clinical setting in the short term to demonstrate acceptance of prosthetic changes. Prosthetic stance time and T_1 were better indicators of gait consistency, both becoming extended after each knee unit substitution and reducing as time progressed.

More difficult to measure, but equally useful as a gauge of gait stability, was the prosthetic knee angular velocity. This pattern also did not stabilize until after a settling-in period.

Although with the hydraulic knee the subject demonstrated a higher quality gait, as evidenced by the smaller T_1 and less variable knee angular velocity, he elected to continue using the prosthesis with the friction knee. This somewhat surprising result may be explained by the increased variability in hip power for condition 1 (hydraulic knee), which indicates a high energy input at the hip when this knee unit is used.

CONCLUSIONS

From the data presented in this study, it can be demonstrated that the subject became more consistent in his walking pattern the longer he used the prosthesis.

It is thus recommended that prostheses that have been altered should be worn for at least one week before consideration is given to accepting or rejecting the changes made. Further, for research purposes, a period of 3 weeks familiarization on the prosthesis is more appropriate.

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Conventional 4-bar linkage knee mechanisms: A strength-weakness analysis

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PREFACE

Experts with completely different backgrounds are working on prosthetic and orthotic components. *Manufacturers* generally develop new components by hiring biomechanical engineers. *Biomechanical researchers* (engineers) carry out fundamental and applied research in the field of prosthetics and orthotics. *Medical doctors* prescribe prostheses and orthoses, *prosthetists* and *orthotists* individually fabricate, fit, and align them, *physiotherapists* train the users on the use of these devices.

Until now, medical doctors, prosthetists, orthotists, and physiotherapists worked primarily on an empirical basis with regard to prosthetic and orthotic components. The producers of the above-mentioned components provide (along with their products) only the technical specifications concerning the material and construction used in the components; they do not provide insight in those aspects, which are, or could be, relevant for *non*technicians.

For years, biomechanical researchers have been busy building up their knowledge of factual insight in prosthetic and orthotic components. This insight reaches only a small segment of nontechnicians. The reason for this could be lack of interest, but it is more likely that the content of scientific publications aimed at biomechanical engineers is not sufficiently accessible and the publications pay insufficient attention to this aspect.

As far as nontechnical research is concerned (e.g., research into the comfort of users of prosthetic components), the results are seldom to be found in applied biomechanical research. Hence, technicians and nontechnicians are working in this field of prosthetics and orthotics independently of each other. The Department of Biomechanical Engineering of the Twente University in the Netherlands, is trying to change this situation, by collaborating with the Rehabilitation Center Het Roessingh.

The following article about the clinical meaning of a study concerning a strength-weakness analysis of the conventional 4-bar linkage knee mechanisms is a result of this collaboration. Biomechanical data of the 4-bar linkage knee mechanisms are translated into their clinical relevance and combined with clinical insight (pathology). The translation of biomechanical knowledge into clinical terms (in this case by a medical doctor) makes it almost inevitable that discussion will arise regarding certain clinical interpretations; there may even be different opinions between technicians and clinicians.

On behalf of a mutual development of insight in the approaches to a certain research subject by holders of different opinions, it is useful that discussions about the above-mentioned subject are not avoided. Discussion can contribute considerably to the development of integral research by technicians and nontechnicians in the field of prosthetics and orthotics.

Abstract—The purpose of this article is to inform clinicians of the relevant knowledge gained from research in the field of prosthetics. From a biomechanical point of view, clinicians need relevant knowledge in order to properly prescribe a lower limb prosthesis, including prosthetic components. In this context, and due to the lack of data regarding their utility, a strength-weakness analysis of 8 types of 4-bar linkage knee mechanisms has been carried out.

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A paper on this subject was presented by Dr. de Vries at the 7th World Congress of the International Society for Prosthetics and Orthotics, June 28–July 3, 1992, in Chicago, IL.

Free-moving knees are intrinsically stable in the stance phase of walking when the 0° center of rotation is behind the femur head to heel line. This was found in 5 of the 8 knees. Furthermore, bending the knee at toe-off requires force. The hip-flexion–torque required is smaller when the 0° center of rotation is closer to the femur head to toe line and is dependent on the measure of axial load. Comparatively, however, much energy is usually still necessary. This can be improved. The maximal axial residual limb load, the maximal hip-moment, and the energy required are, on investigation of the knees, approximately the same in relation to the walking speed during the swing phase of gait. Friction influences the swing characteristics of the prosthetic lower limb considerably. In this context, little is yet known about swing phase knee control units.

The present 4-bar linkage knees-with-lock are a derivation of the free-moving knees. Their movement characteristics, and often heavy construction, are of no relevance when walking with a fixed knee. In proportion, much energy is required. Therefore, there is a demand for a simple knee mechanism that moves freely during the swing phase, locks at the beginning of the stance phase, and unlocks at the end of it.

Key words: *above-knee amputees, biomechanics, 4-bar linkage knee mechanisms, through-knee amputees.*

INTRODUCTION

Since the introduction of the 4-bar linkage knee mechanism, approximately 20 years ago, it has been increasingly applied to persons with above-knee (AK) and through-knee (TK) amputation. Like the single-axis knee mechanism, various 4-bar linkage knee mechanisms, differing in construction and material, have since been put on the market by the industry. Until now, the product information about these 4-bar linkage knee mechanisms has been restricted to insufficient guidelines regarding construction and loadability. There is a lack of data that can give insight to prescribers and users of AK and TK prostheses into the subject of utility. How do the 4-bar linkage knee mechanisms influence the function, comfort, and cosmetics of the prosthesis? Using clinical and biomechanical research data (with the help of prosthetic-walking–computer models), a strength-weakness analysis of 4-bar linkage knee mechanisms has been carried out.

METHOD

Strength-Weakness Analysis

From a functional point of view, it is well-known to clinicians, that first of all, persons with AK or TK amputation want to walk safely: meaning without danger of a sudden flexion of the prosthetic knee.

If the person with AK or TK amputation is not walking safely enough (1,2), or is afraid to walk with a "free moving" knee mechanism, then a knee mechanism with knee-lock is applied. For the person with AK amputation, a simple uni-axis-knee with knee-lock of about 300 g would be prescribed, and for the person with TK amputation, a 4-bar linkage knee mechanism with knee-lock of about 550 g (carbon) up to 850 g (steel). This is a heavy knee mechanism compared with the uni-axis-knee with knee-lock. It means a negative influence of the wearing comfort of the prosthesis (more weight). The only reason to use the heavy 4-bar linkage knee mechanism is a cosmetic one. When applying a uni-axis knee with knee-lock, the upper limb part becomes too long compared with the sound upper limb. This is noticeable when the person is seated. When using a 4-bar linkage knee mechanism, this is less noticeable.

When most persons with AK amputation use a free-moving knee mechanism (3–5), a 4-bar linkage knee mechanism—as well as a uni-axis knee mechanism—can be applied. In cases of persons with TK amputation, one has to apply a 4-bar linkage knee mechanism. The uni-axis knee mechanism has a fixed center of rotation, while the 4-bar linkage knee mechanism has a collection of instantaneous centers of rotation. Many physicians prescribing AK- and TK-prostheses are not familiar with the trajectory of the instantaneous center of rotation of 4-bar linkage knee mechanisms applied. A 4-bar linkage knee mechanism is intrinsically extension-stable, meaning without extension of residual limb force, if the 0° center of rotation of the knee mechanism is situated behind the straight line from the femoral head to the heel (**Figure 1a**).

Figure 2 shows the graphs of the collection of instantaneous centers of rotation of 8 knee mechanisms (BOCK 3R36, TEHLIN, PROTEOR 1MO3, PROTEOR 1M02, PROTEOR 1M05, BOCK 3R21, HANGER ROELITE, and HANGER ULTRA ROELITE).

Each trajectory begins with the 0° center of rotation. If **Figures 1a** and **2** are combined, then one can determine that the 0° center of rotation of 5 of the 8 knee mechanisms is situated behind the above-mentioned femoral head to heel line.

A uni-axis foot prosthesis (6), which lands flat on the ground directly after heel strike, causes the femoral head to heel line to turn to the right (line from the femoral head to center of the foot prosthesis). Hence, in this manner, this type of foot prosthesis increases the extension-stability at the beginning of the stance phase. Moreover, one can also

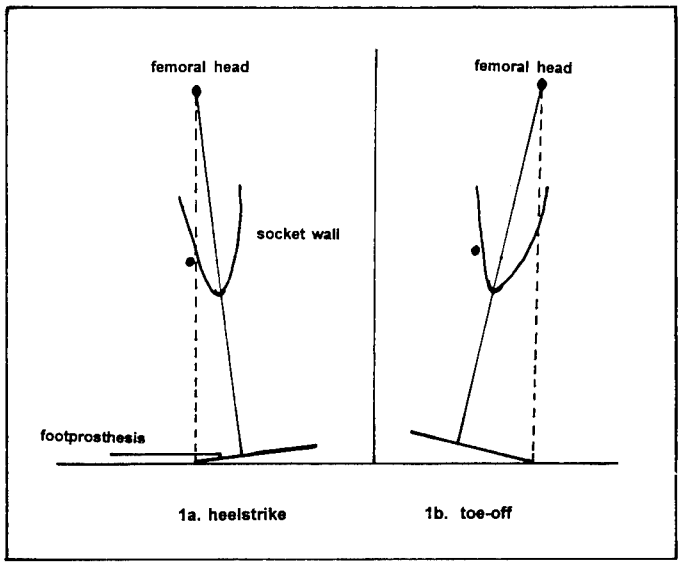

Figure 1.
Scheme concerning the role of the 0° center of rotation of a 4-bar linkage knee mechanism at heel strike and toe-off.

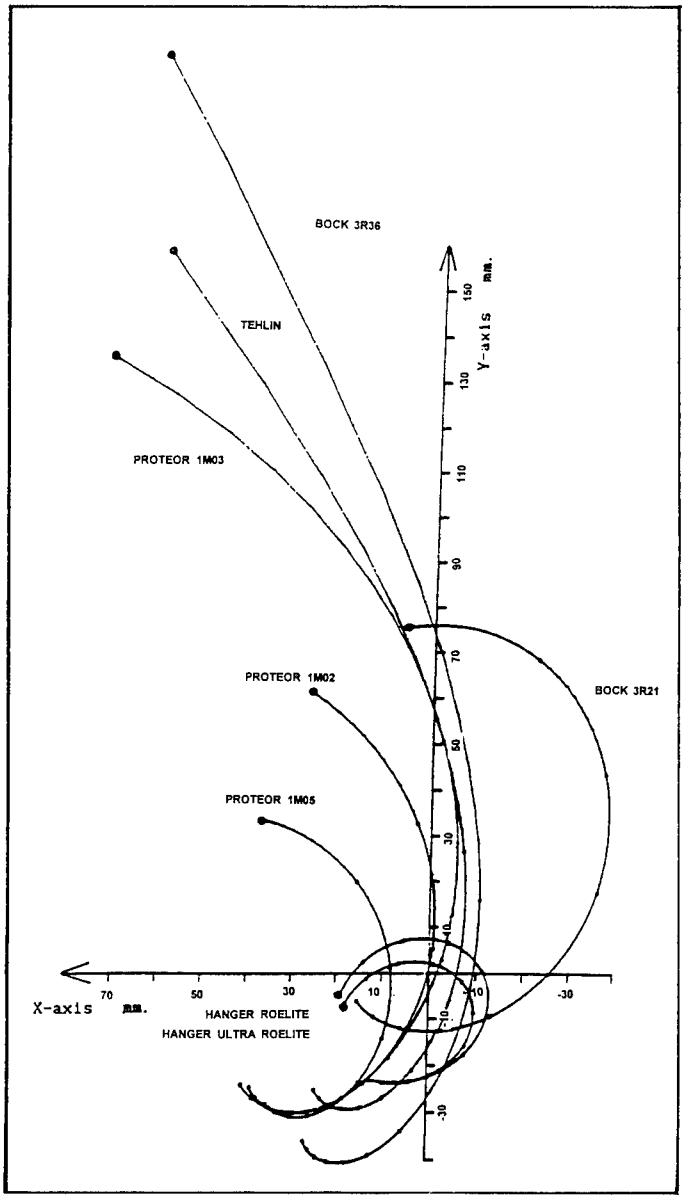

Figure 2.
Trajectory of the instantaneous center of rotation of 8 common knee mechanisms (BOCK 3R36, TEHLIN, PROTEOR 1M03, PROTEOR 1M02, PROTEOR 1M05, BOCK 3R21, HANGER ROELITE, and HANGER ULTRA ROELITE).

influence the extension-stability by shifting the 0° center of rotation horizontally to dorsal, by means of moving the knee mechanism dorsally. A vertical shifting has very little influence on the extension-stability.

With regard to 4-bar linkage knee mechanism, the uni-axis knee mechanism is normally less extension-stable (center of rotation on or just behind the femoral head to heel line).

When the knee has to be flexed, at the moment of toe-off (**Figure 1b**), this costs hip flexion torque. This varies in any type of knee mechanism. The magnitude thereof can be influenced by shifting the 0° center of rotation horizontally and is dependent on the measure of axial load of the prosthetic limb. When the 0° center of rotation is closer to the femoral head to toes line, a smaller hip-flexion torque is needed. This amounts, on average, to 36 percent (based on model studies) of the axial load of the prosthesis at the toe-off. It is important that clinicians have knowledge of this, because the hip flexion torque initiating knee flexion is often much more, and then it is doubtful whether the residual limb can produce this force. If not, then the prosthetic limb has to be relieved, meaning less or no axial loading. Using a uni-axis knee mechanism, the hip-flexion torque required is usually smaller than with most 4-bar linkage knee mechanisms. The difference is smaller when the 0° center of rotation is higher and close behind the femoral head to heel line. If the 0° center of rotation is beyond the femoral head to toes line, there is no force required to bend the knee. Theoretically, a small knee flexion (< 20 g) at the end of the stance phase of the knee mechanisms investigated is possible before the position of the instantaneous center of rotation arrives beyond the femoral head to toes line. But in practice, the onset of the swing phase starts with a totally extended knee.

Both the prosthetist and the rehabilitation clinical specialist (MD, PT) should have knowledge of the factors

determining the stability of prosthetic knees at the beginning and the end of the stance phase. Together they choose the right prosthetic components, based on the user's experience with a temporary prosthesis, and realize the optimal alignment.

The swing phase is next (7–11). Above all, clinicians pay attention to the energy consumption during the swing phase: the factors that act upon it, such as the length of the prosthetic limb, the weight, and the friction resistance of the knee mechanisms, respectively. But, in fact, they do not know which factors are relevant for their clinical practice. Using prosthetic-walking computer models, the limb-shortening effect of the knee mechanisms due to kinematic properties appears, with regard to mechanical energy, to be zero or minimal (10 percent). This means that the effect on the vertical translation of the femoral head is small or nonexistent. Researching the relation between, on the one hand, the maximum axial (**Figure 3**) residual limb load, the maximal moment at the hip (**Figure 4**), and the energy (**Figure 5**) required during the swing phase and on the other hand, the walking velocity, we found no significant differences between 4-bar linkage knee mechanisms (BOCK 3R36, PROTEOR 1M03, PROTEOR 1M02, PROTEOR 1M05, BOCK 3R21, HANGER ROELITE, and HANGER ULTRA ROELITE). Uni-axis (Bock-uniaxal) knee mechanisms seem to have the same features.

Three causes are responsible for the overall knee torque flexing or extending of prosthetic knees (12): the moment of inertia, the spring force, and the friction resistance. Research on the influence of spring- and friction adjustments on the flexion-extension rigidity of 4-bar linkage knees shows that the friction adjustment has clearly much more influence on the knee rotation resistance than does the initial stress of the spring. For example, the torque-displacement curves of one of the prosthetic knees (PROTEOR 1M03) investigated are presented in **Figures 6** and **7**.

On the horizontal axis, the knee-angle is presented in degrees from 0° to 60°. The torque exerted on the knee stands vertically in positive direction of the flexion force and negative in the extension torque. In both figures, the upper group of curves are flexion curves and the lower group extension curves. If one of the extension curves rises above the 0 Nm axis, this means that during extension a flexion-torque is needed to decelerate the rotation of the prosthetic knee. Due to bad adjustability of the prosthetic knee, the levels of friction and spring-stress could only be chosen roughly as low, medium, or high.

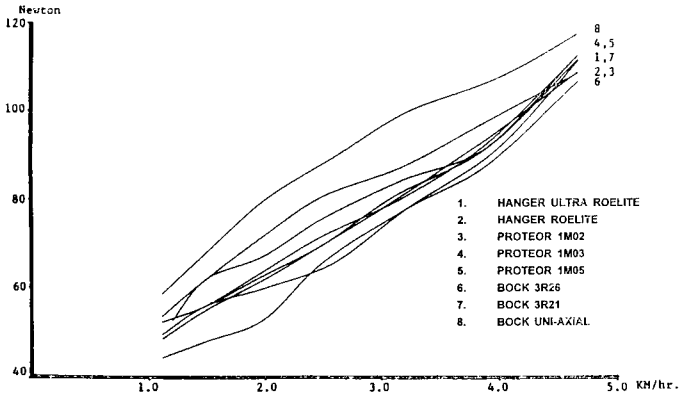

Figure 3.
The maximal axial residual limb load plotted against the velocity for 8 knee mechanisms.

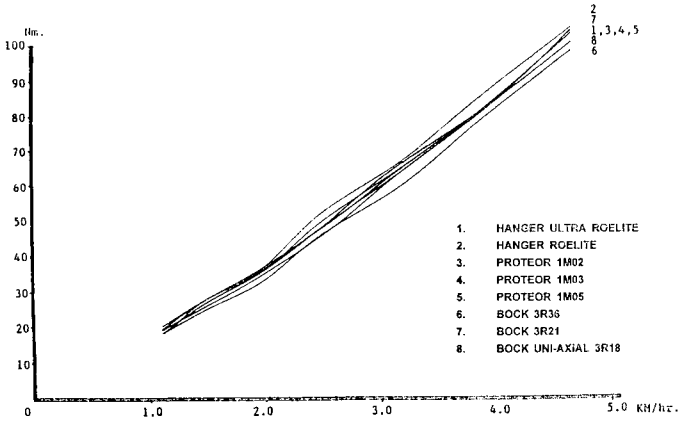

Figure 4.
The maximal moment at the hip, plotted against the velocity for 8 knee mechanisms.

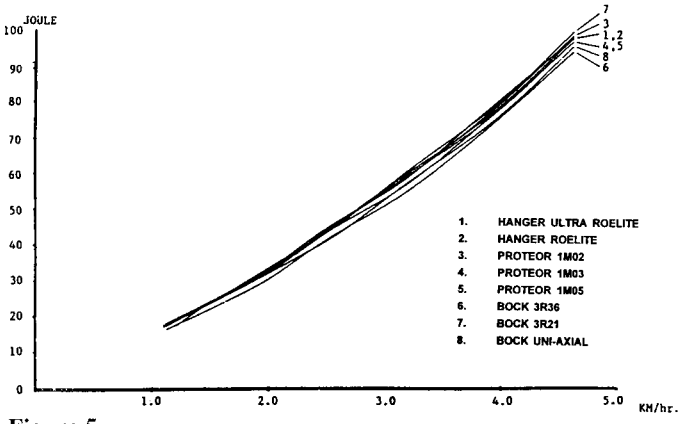

Figure 5.
The energy required during the swing phase, plotted against the velocity for 8 knee mechanisms.

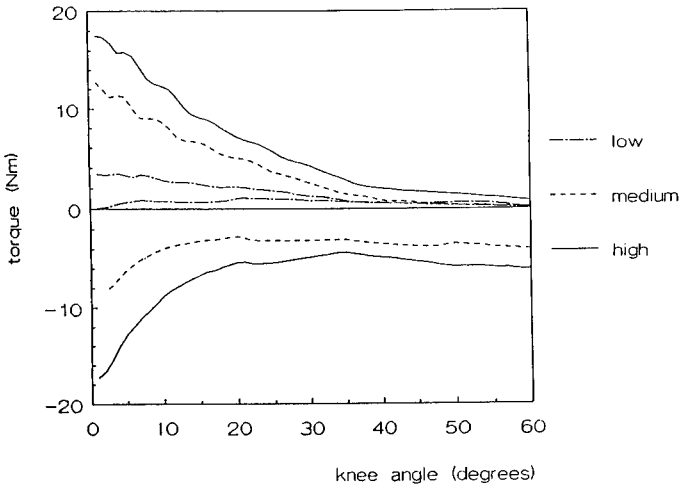

Figure 6.
Friction influence—PROTEOR 1M03, low spring stress.

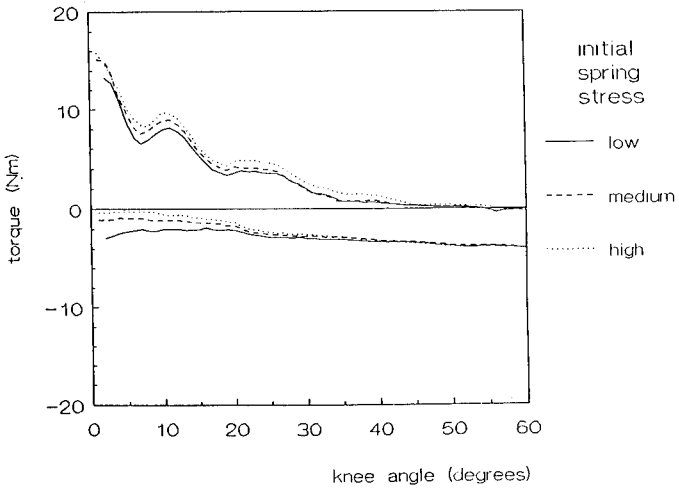

Figure 7.
Spring stress influence—PROTEOR 1M03 (1 Hz, medium friction).

DISCUSSION

Looking at the above-mentioned results of biomechanical research, it appears important for clinicians to pay attention to the factor of friction resistance. Regarding the question of choosing a free-moving knee mechanism from a functional point of view, a 4-bar linkage knee mechanism is (considering the above-mentioned arguments) preferable for most rehabilitation clients, especially elderly persons with amputation, in order to guarantee that they walk safely; that is, being stable without danger of sudden flexion of the knee mechanism (13,14). For this reason, a knee mechanism with an intrinsic stability at the heel strike is necessary.

Shifting the 0° center of rotation horizontally, we look for the optimal position, taking into account the intrinsic stability and the torque needed at the toe-off. Only in the case of young people with AK amputation is it responsible to experimentally use a single-axis-brake knee mechanism.

With regard to the swing phase in walking (when looking at the swing-characteristic of the 4-bar linkage knee mechanisms), friction seems, functionally, the most important factor. In this context, the role of a swing phase control is not yet well-known (15).

Above all, the younger rehabilitation clients, on average, subjectively experience this added function as positive. But, do function (energy consumption) and cosmetics (walking more naturally) complement each other in this case? Due to the lack of knowledge, it is responsible to be reserved in prescribing the expensive knee mechanisms with a swing phase control unit at this time.

The application of knee mechanisms made of steel or duraluminium is preferred. Using titanium or carbon, the same knee mechanisms can be lighter, but are also more expensive. In our contact with rehabilitation clients, we found that their experience with the weight of a prosthesis in general, and the knee mechanism in particular, plays an important role. The prosthetic components industry anticipates this by presenting lightweight knee mechanisms. The objective advantage of lesser weight is not evident: for example, what is the influence on the energy consumption of the amputee? (15–17)

Considering the weight of a limb prosthesis, we do not say this factor is not of interest in any way. However, recent research into the weight of the lower limb prostheses (18,19) points especially in the direction of the importance of the weight distribution factor at the level of the lower limb part of an AK- or TK-prosthesis. Each individual has an optimal oscillation of the lower limb part of his or her prosthesis, depending on the amplitude of the comfortable walking speed. The optimization of this oscillation can occur by means of fitting a more or less heavy foot prosthesis, respectively making the tube of the lower limb part heavier (distally of the center of mass of the prosthesis). Starting from the point of oxygen-consumption, walking with a heavier AK prosthesis with an optimal weight distribution appears to consume less energy (18), than walking with a nonoptimally lightweight AK prosthesis.

In an objective sense, the significance of the weight of a knee mechanism is comparative. With regard to a person with AK amputation, the weight of the part of the limb amputated is ± 10 kg. Today, a simple geriatric AK prosthesis has a weight of about 2–2.5 kg, which is less than 25 percent of the weight of the original part of the limb. Objectively, one can speak of a lightweight construction, but in practice we see that the elderly person with amputation often complains about a heavy prosthesis, although the weight is only, for example, 2.25 kg. In this case, one will usually be confronted with an insufficient fitting of the socket, which stays on the residual limb due to a rigid pelvic band (RPB) or a trunk bandage. If this socket can be replaced by an adequate suction-socket, one will see that the "problem" of the heavy socket has been reduced or has even disappeared, in the eyes of the person with amputation, although the weight of the prosthesis remains 2.25 kg.

This example shows the great significance of an optimal connection of the residual limb to the socket, in relation to the perceived experience of the weight of the prosthesis. It also tells that the significance of the weight of the prosthesis components (e.g., the knee mechanism, distally of the AK-socket) is of relative importance regarding the wearing comfort of the limb prosthesis. Expensive lightweight products (e.g., a titanium knee mechanism) are not the right solution to solve the problem of the subjectively heavy limb prosthesis (20). The above-mentioned points regarding the weight factor are reason enough, at this moment, to disregard this factor when choosing a knee mechanism.

CONCLUSION

In several respects, the 4-bar linkage knee mechanism can still be improved. With free-moving knee mechanisms, there is a need for types that allow a safe stance phase, have a low energy-consumption, present a natural swing characteristic during walking, and are as light as possible (using standard products). Stance phase safety can be adequately realized by the use of the 4-bar linkage knee mechanism. This demands no energy during the first half of the stance phase. Unfortunately, the present-day 4-bar linkage knee mechanisms need (looking at the results of model calculations) much hip flexion torque (in relation to walking normally) to flex the knee mechanism at the end of the stance phase.

A research project has been started at the Twente University, in the department of biomechanical engineering, that is aimed at developing a 4-bar linkage knee mechanism that can be flexed with as little energy as possible (hip-flexion) at the end of the stance phase. This can take place when the instantaneous center of rotation is situated just behind the femoral head to toe line at the toe-off, and preferably as high as possible above the knee level.

The present-day 4-bar linkage knee mechanism-with-lock has been derived from the free-moving 4-bar linkage knee mechanism. This construction, made of steel with a weight of ± 850 g, has been developed to meet certain functional demands which are, however, not relevant when walking with a "stiff" knee (with lock). A specific knee mechanism-with-lock should be developed, which can also be simplified and be lighter in weight than the present-day 4-bar linkage knee mechanism-with-lock.

A disadvantage of the knee mechanism-with-lock is, however, that walking with a stiff knee consumes more energy than walking with a free-moving knee. Taking this into account, a lightweight, single-axis knee mechanism has been designed which moves freely during the swing phase, locks at heel strike and unlocks at toe-off. The first prototypes of this knee mechanism are already in use experimentally. The clinical experiences are promising.

Before the above-mentioned 4-bar linkage knee mechanism now in development can possibly be supplied with a swing phase control unit or another solution, insight will first have to be gained about the influence of these units on the swing-characteristics of lower limb prostheses, especially from an energetical point of view. At present, this item is the subject of research at the University of Groningen, in the Department of Rehabilitation.

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Waking effectiveness of visual alerting signals

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Abstract—People who are unable to hear acoustic alarm signals because they have a complete or partial hearing loss must rely on visual or tactile signals to warn them in the event of an emergency. However, consumers report that personal smoke detector devices which provide a visual alarm do not wake people reliably. We examined the ability of visual alerting devices to wake people from the deepest stages of sleep: slow wave sleep (SWS) and rapid-eye-movement sleep (REM). These results were related to the physical (optical) characteristics of devices currently on the market. In Experiment 1, a range of strobe intensities and locations were investigated. Experiment 2 confirmed the results of this pilot study on an independent set of subjects. On each trial, the strobe was allowed to run at a constant intensity until the subject awoke, or a maximum of 5 min had elapsed. Even though a diffuse light remained directly over the subject's face for each trial, subjects did not wake consistently. Under the favorable optical (smoke-free) conditions of the present study, the most intense of the devices presently offered for sale in Canada cannot be relied on to wake a sleeping person in the event of a fire. It remains unclear whether any visual alerting device can be expected to safely wake a sleeper in an emergency situation.

Key words: *deafness, hearing loss, sleep arousal, smoke detector alarms, visual arousal thresholds.*

INTRODUCTION

Every year, 80,000 Americans die or are injured in fires. Most fatal fires occur at night when the victims are asleep (1). A study of multiple death fires indicated that more than 80 percent of them occur between 8:00 p.m. and 8:00 a.m., with the largest number (40.5 percent) between midnight and 4:00 a.m. (2). These considerations make smoke alarms an important part of fire safety planning.

In approximately 95 percent of fire incidents, serious injury or death is prevented by use of a fire safety alarm (1). There are three primary options for alerting the sleeper in the event of an emergency: auditory, tactile (vibrational devices, or fans), and visual. While emergency and warning signals are commonly acoustic, these are not appropriate for persons who are deaf or hearing impaired. Approximately 8 percent of the North American population is hard of hearing, having serious difficulty perceiving acoustic signals and alarms when not wearing amplification (3). An additional number will have significantly reduced ability to hear such signals and alarms due to a partial hearing loss.

The most common alternative to acoustic alarms is a visual alarm. However, deaf and hard-of-hearing consumers report that the strobes typically used in family dwellings cannot be relied upon to alert them in the event of an emergency.[1] Manufacturers, however, feel that the needs of consumers are being met. A recent study by Nober et al. (4) suggests that deaf people receive about the same levels of protection from strong visual smoke alarm strobe signals as hearing persons receive from audible smoke alarms: in their study, 90 percent of the deaf subjects were awakened by strobe devices. Unfortunately, these results are inconclusive because (*a*) they did not control for the stage of

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[1] Personal communication with J. Beattie, January 1992.

sleep during which the stimulus was presented, and (*b*) they relied on self-report measures as to whether the subjects were awakened by the flash unit or by another member of the household. There remains, therefore, a clear need to assess the effectiveness of smoke detector systems that provide a visual alarm.

Underwriter's Laboratories (UL) has undertaken research relating to standards for fire emergency signalling to alert people who are hard of hearing. One part of this study was designed to assess performance with a flashing strobe in an otherwise dark room. The study demonstrated that some subjects were temporarily blinded, or sufficiently disoriented by the flashing light that they failed to complete even simple tasks (5).

In a nighttime bedroom study (home or school dormitory), deaf persons were alerted with a strobe device which operated for 4 min and then shut off (5). The chosen time frame corresponded to the minimum alarm duration specified by UL for battery operated smoke detectors. A flash repetition rate of 1 Hz was used, since slower rates, presented in a dark room, have lead to disorientation and confusion. The alarms were activated randomly between 1 a.m. and 4 a.m. If the subject woke up, he or she recorded the time of waking, which was later compared to the initiation time of the alarm. The intensity of the strobe was adjusted up or down depending on its effectiveness, until a threshold point of detection was located. It was reported that 92 percent of test subjects (not using medication) were alerted by a strobe light that was 110 candela (cd), while subjects using medication were awakened only 28 percent of the time.

Whether or not such an alarm can wake a person reliably is not clear (6). Moreover, it is clear that any such alarm must act quickly: once a flame has entered the room, a fire can engulf the entire room in as little as 2 min. Carbon monoxide can build up during a fire and enter the blood stream, causing persons to become disoriented (3). Such considerations emphasize the need for effective systems to warn hard-of-hearing and deaf persons of the presence of a fire. Visual alarms, such as flashing lights, however, may be ineffective since they may be out of the field of vision, or the user may be asleep. For hearing people, single unit audible alarms are typically mounted outside the sleeping area. For deaf or hard-of-hearing people, a single alarm would need to be placed inside the sleeping area, so that smoke must enter the bedroom before the smoke alarm signal is triggered. These considerations underline the need for a reliable, fast-acting alarm system.

An alternative to acoustic or visual alarms is to use a tactile signal (7), such as a signal-activated vibrator (placed between the mattress and box spring or under a pillow). Such devices are reported to be effective at alerting sleepers, but vibration devices have not been approved as safety devices (3), and some vibratory devices must be worn and may, therefore, be easily forgotten. Consequently, vibratory devices may be a less suitable choice for alerting persons in emergency situations.

Canadian Standards

At present, there are no known standards or codes relating to the use of nonauditory alarm systems in Canada. Neither the Canadian Building Code nor the Fire Code addresses the problem of sleep arousal. A task group has been formed under the Standing Committee on Occupancy for the National Building Code to look into the issues regarding fire alarms, including the problem of arousal from sleep; however, their mandate is restricted to audible alarms only.[2] Moreover, the available international standards define criteria applicable only to the recognition of audible signals (8,9).

American Standards

In the United States, several codes address smoke detectors, but do not include specifications for visual signals from these detectors (10). The Americans with Disabilities Act (ADA) (11) provides comprehensive civil rights protection to "individuals with disabilities in the areas of employment, public accommodations, state and local government services, and telecommunications." The *Federal Register* (Section 4.28), states minimum photometric standards for visual alerting devices to be "white xenon strobe or equivalent, intensity (75 cd), flash rate (1–3 Hz), pulse duration (0.2 s), and location features. However, a higher level (110 cd) may be required to alert sleeping persons (Section A4.28). UL upgraded this standard to a minimum of 177 cd; however, this has not been legislated within the ADA.[3] Devices with the 177 cd rating are said to be authorized to be labelled as "smoke detector for the hearing impaired."[4]

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[2] Personal communication with R.E. Halliwell, March 1992.

[3] Personal communication with L. Johansen, Accessibility Specialist, Office of the Americans with Disabilities Act, December 21, 1993.

[4] Personal communication with D. Parsons, Manufacturing and Marketing, Ven-Tek, Inc., September 24, 1993.

Visual Smoke Detectors on the Market

Manufacturers offer a wide range of intensity levels on their strobe signals ranging from 1.5 to 117 cd (Wheelock Inc.) and 120 cd (Gentex Corporation), with such features as audible signals offered as options. Hard-wired systems (smoke detector, transmitter, and alerting device) are available along with the portable option. Warnings have been placed on specification sheets for these lower-intensity devices so that people are aware of the fact that "the intensity of the strobe may not be adequate to alert or awaken occupants in the protected area" (12). Manufacturers, however, are discontinuing many of these devices and replacing them with devices which meet the latest standards. The first manufacturer to meet the 1992 UL requirements was Ven-Tek. Accordingly, the specifications for this device read "smoke detector for the hearing impaired." This device is available as a portable or hard-wired device, 180 cd, with a flash rate of 65–75 cycles/min.

Description of Sleep and Wakefulness

Standard polysomnographic criteria for sleep and wakefulness are defined in Rechtschaffen and Kales (13). Quiet and active sleep can be defined further with respect to these criteria.

Quiet sleep, synchronized, slow-wave-sleep (SWS) or non-rapid-eye-movement (NREM) sleep, has an EEG characterized by high-voltage waves with slow frequencies. Neck and chin electromyograms (EMG) indicate a reduced but apparent muscle tone. There are four substages of quiet sleep in humans (14). Nober, Peirce and Well (15) claim that SWS and rapid-eye-movement (REM) sleep stages alternate, with REM recurring about every 90–110 min during sleep. Remmers (14) described Stage 1 as characterized by a loss of alpha waves; Stage 2 is denoted by the presence of sleep spindles and K-complexes; Stage 3 is marked by high-amplitude delta activity; and Stage 4 contains more than 50 percent delta activity.

Active sleep (desynchronized, paradoxical, or REM sleep is accompanied by low-voltage, mixed frequency EEG tracing, intermittent REMs and a sustained suppression of neck and chin EMG tracing. Muscle twitching, fluctuations in penile tumescence, and loss of deep tendon reflexes are also characteristic of this stage (14). In addition, rhythmic contractions of the middle ear muscles have been noted (16, 17). Essentially, REM sleep is a stage of heightened EEG activity which recurs every 90–110 min (18). During REM sleep we are almost completely paralyzed. Only the heart, diaphragm, eye, ear, and smooth muscles are spared from this paralyzing effect (19).

Sleep researchers distinguish the tonic and phasic events of REM (20). Molinari and Foulkes (21) proposed a two-factor model of stage-REM based on presumptive support at the psychological level. It is their contention that "periods" of stage REM are unified in their tonic dimensions but phasically heterogeneous. Phasic events occur in conjunction with intense central excitation and are associated with decreased responsiveness to afferent stimulation. This was demonstrated by consistently smaller auditory evoked responses (AER) during bursts of ocular activity (22). Much of the dreamlike nature of stage-REM mentation derives from "phasic activation" in stage REM. Molinari and Foulkes (21) postulated that nonphasic REM may be similar to episodes of NREM sleep, and the phasic activation of stage REM may not be entirely limited to that stage. They suggest that this tonic-phasic distinction provides a means for recognizing important intra-REM variations and similarities as well as differences between stage REM and other sleep stages.

In an entire night, 4–6 REM periods are expected to occur variably across subjects (23), beginning after one or two hours of NREM sleep (24). REM phases become progressively longer toward morning. Conversely, NREM occurs more frequently and is deeper in the early part of the night and becomes shallower and shorter toward morning (25). Thus, it was proposed that the length of the REM period confounds the analysis of early versus late REM trials (26), making it difficult to discern how length of the REM period relates to the awakening threshold.

Arousal During Sleep

The ease with which people can be awakened varies as a function of stage of sleep (15). In Stage 1, people are easily awakened by noise or a voice. During Stage 2, the person is sound asleep but is still easily awakened. In Stage 3, an intense stimulus is required to awaken a person, while irrelevant stimuli do not disturb sleep. Finally, Stage 4 requires even more intense stimuli to awaken a person, and once awakened the person becomes alert slowly. Rechtschaffen et al. (26) reported that the threshold of arousal increases from the first to the second phase, but there was no significant difference between arousal thresholds during phases 2, 3, and 4. Zung and Wilson (27) contended that in the deepest or "E" stage of sleep, discriminative ability is present but reduced compared to other stages of sleep.

Remmers (14) contends that sleep moves in an orderly sequence from Stages 1 to 4 of quiet sleep and in doing so progresses to increasingly deeper sleep. Sleep stages are distributed differentially over the night such that there is more time spent in SWS early in the night, and more time spent in REM in the later half of the night.

The presence of alpha waves is associated with momentary arousals. Alpha increases and behavioral responses combine to identify microarousals from sleep with increased precision (28). Less alpha occurs in the second half of the night. Both of these may allow the subject to be physiologically aroused more easily in the first half of the night (29). During the night, cumulative REM as a percentage of total sleep time gradually increases from 3 percent during the first hour to 24 percent by the seventh hour. Cumulative total SWS decreases from 55 percent to 22 percent during the night (30). Thus, SW activity declines over time (31). Stage 1 sleep remains nearly constant across the night at 5 percent. Stage 2 is nearly constant after the second hour at 49 percent. The average sleeper awakens 8 or 9 times in a night, for at least 15 sec, and awakens 80 times a night for at least 2 sec (32). These arousals are usually accompanied by increases in alpha activity; arousals lasting less than 1–2 min are seldom recalled in the morning.

Research using painful electrical stimuli demonstrated that the threshold of arousal from sleep varies during the night, within a single phase of sleep (33). The most stimulation was required to awaken people in Stages 3 and 4. With olfactory stimuli, behavioral and EEG arousals were elicited more frequently in Stage 2 than in REM sleep or Stage 4 sleep (34). In Stage 4, the threshold for auditory smoke alarms ranges from 60–120 dB (35). Smoke alarms produce an 85 dB signal, with an additional loss of approximately 15 dB by passage through a closed door. Therefore, it is questionable whether an auditory alarm would awaken hearing persons in all stages of sleep.

In general, people are difficult to awaken from REM sleep (19). The unprovoked arousal from REM sleep is comparable to Stages 1 and 2 (NREM sleep), while arousal from SWS occurs less frequently (36).

Rechtschaffen et al. (26) claim that the waking threshold decreases as the amount of accumulated sleep increases. When split into 3.5 hour divisions, waking was more frequent during late REM trials than during early REM trials. Waking thresholds were similar for REM periods and Stage 2, but both had lower waking thresholds than delta sleep.

In contrast, Badia, Wesensten, and Lammers (37) reported that subjects were less responsive to olfactory stimuli during the last third of the night than in the early or middle parts of the night. Johnson et al. (38) reported that in the early morning, average arousal threshold was highest in Stage 4, and lowest in either Stage 2 or REM sleep. With no consistent differences between Stage 2 and REM, good and poor sleepers did not differ in arousal threshold, regardless of sleep stage.

Nober et al. (15) reported the arousal was not a function of gender, time of night, or day of the week and Rechtschaffen et al. (26) found no general systematic relation to waking threshold with body temperature, respiratory rate, heart rate, or skin resistance. Wilson and Zung (39) reported that women were more easily aroused from sleep than men by neutral nonmotivating auditory stimuli, although arousal threshold to significant sounds did not differ. Meaningful auditory stimuli were not differentially effective across sleep stages, although auditory awakening thresholds tended to be higher during Stage 4 sleep (40).

Previous studies concerning the effects of sleep laboratory adaptation noted that when normal subjects spent two nights in the sleep laboratory, there were significant changes noted on the second night of the study. Specifically, it was noted that 1) the amount of time spent "awake" and "drowsy" decreased; 2) time spent in Stage 3 increased; 3) the latency to the first REM period and the first Stage 3 sleep period were reduced; and 4) the number of REM periods increased slightly on the second night (41).

Central Processes

Wilson and Zung (39) claim that three central processes underlie arousal from sleep:

1. the stimulus must be received by the appropriate sensory organ passed to the cerebral cortex;
2. the stimulus must be analyzed by the cerebral cortex for importance and content;
3. if the stimuli are personally significant, corticofugal impulses are sent back to the reticular formation, which in turn may evoke arousal.

Rechtschaffen et al. (26) suggested that signals can be detected without waking if the response is incorporated into a dream. Incorporation of stimuli into dreams may be a concern when signals are presented below waking intensity and gradually increased, increasing waking thresholds during REM periods. During NREM sleep, K-complexes can be observed in EEG recordings in response to external

stimuli, indicating that the stimulus registered without observable behavioral or alerting responses on EEG activity. But, Salisbury and Squires (42) conclude that data are insufficient to determine whether K-complexes reflect arousal and desynchronizing mechanisms or antiarousal and oscillation enhancement mechanisms.

Visual Alarm Signal Specifications

Color

Nober et al. (1) recommended that white strobe flashes be used in visual alarm systems for waking people.

Temporal Pattern

In standardized audible warning signals, the International Organization for Standardization specified a "three-pulse" temporal pattern, consisting of an "on" phase of 0.5 sec ± 10 percent, sounded for three successive "on" periods, followed by an "off" phase lasting 1.5 s ± 10 percent (9). It is not known whether these patterns could be generalized to visual and tactile signals to aid those who are hearing impaired and/or work in intense background noise where acoustic warnings are inaudible.

Rate

UL (43) recently published standards for signalling devices for the hearing impaired. One requirement is that the strobe signal flash at a rate between 1 and 3 Hz. A task force has recommended that the ANSI-1980 standard be modified so that flashing lights for visual alarms operate at approximately 1 Hz (10). Higher rates of flashing may induce epileptic seizures, with effective flash rates reported to be 8–20 Hz or 10–25 Hz (44,45). Such photosensitivity is greatest between 5–24 years of age (1 in 4000), but has also been reported in infants and the elderly (46). A separate manufacturing and consumer concern is that higher flash rates decrease the life of the bulb.

Intensity

If the mounting height is within 24 in (61 cm) of the ceiling, and the detector and signalling device are in the same room, the intensity of the signal, required by UL (43), is 177 cd. If the signal is placed more than 24 in (61 cm) from the ceiling, the required intensity is 110 cd. It is not clear on what basis these standards have been developed.

Location

Placement of a visual strobe near the ceiling may be obscured by smoke (10). The strobe light may be more effective if placed near the floor, since this location will not be obscured by dense smoke and gases rising in a room (10).

Duration

According to Bleck (47), both pulse duration and rate influence the perceived brightness of photic pulses. In a study of the brightness of photic pulses which varied in pulse duration and separation, Bleck and Craig (48) found that two pulses separated by 0.02 sec were always perceived as one, and were always perceived as two when separated by 0.04 sec. Maximum brightness occurs for pulses of duration 75 ms to 100 ms.

METHODS

The present study was designed to evaluate the efficacy of currently available, personal smoke detector systems and to identify the parameters of a visual signal which would consistently wake a person from the deepest stages of sleep. Sleep stage was monitored electrophysiologically so that the likelihood of waking in time for safe evacuation in the event of fire, given a specific warning signal, could be determined. Safe evacuation was determined on the basis of the British fire safety code, which designates 2.5 min as the safe evacuation period after discovery (1).

Two experiments were conducted. In addition, the physical characteristics of visual alerting devices currently on the market were measured by an independent testing laboratory and compared to those used in testing. Experiment 1 evaluated the experimental manipulation, including the characteristics of the light source to be tested. Experiment 2 studied the relation between visual signals, sleep stage, and waking in greater detail.

Behavioral testing was conducted in a "state-of-the-art" sleep laboratory. All-night sleep was monitored to ensure that subjects were in periods of SWS and REM sleep prior to the presentation of the visual alerting signals. Strobe flashes of varying intensity were then presented to determine the threshold for waking.

Experiment 1

Approach

This study used the method of ascending limits (gradually increasing light intensity) to explore various aspects of the testing procedure and to obtain initial information relating sleep stage, visual signals, and waking probability. A strobe with a pulse rate of 1 Hz was turned

on at a "low" level after at least 5 min of SWS or REM sleep. Intensity levels varied across trials, as the initial objective was to find an intensity level which would awaken a sleeper within 2.5 min, in accordance with the British fire safety code. Light levels were altered by adjusting the light source in four steps. In the absence of arousal, presentation duration varied between 20 sec and 150 sec.

During subsequent SWS or REM periods, the procedure was repeated, beginning with the strobe at a level which was two steps below the lowest level to which the subject had previously responded. The level was then increased in fixed increments. This procedure was repeated in an attempt to study one SWS trial and one REM trial both early in the night and late in the night, yielding a maximum of four arousals. Sleep stage could not be controlled precisely because in the natural sleep cycle certain stages occur more frequently at different times of night (**Table 1**). Subjects were not asked to evacuate as in previous studies, because electrodes were applied to the scalp so that sleep stages could be monitored. Threshold was defined as the level at which the subjects awoke (opened their eyes and sat up in bed).

It was felt that disruption of sleep beyond four arousals might have an adverse effect on our subjects, and could be too artificial to permit our study to be representative of real-life behavior.

Subjects

Seven young normal hearing women, 18 years or older, were recruited for the first experiment. These subjects had no history of eye disease or epilepsy. All reported that they were "good sleepers" and had normal hearing as confirmed by a test measuring thresholds at octave intervals between 250 Hz and 4000 Hz.

The subjects were recruited through advertisements and posters. An honorarium of 15 dollars was provided for participation in the study. All subjects toured the sleep laboratory and received instructions about the experiment procedure before signing a consent form to participate.

Apparatus

Testing occurred in a 3m × 3m, sound-attenuated, electronically shielded room, illuminated by a red filtered 40 W light source, to minimize intrusiveness. The room was equipped with a single bed, dresser, mirror, closet, and night table. A white strobe flash of variable intensities was mounted above and within 10 ft (3 m) of the sleeper's pillow to provide a diffuse distribution of light regardless of which side the head was facing when the flash was activated. This distance and position helped to ensure constant luminosity at the eye, unless the subject was lying face down (4). **Figure 1** provides a schematic diagram of the laboratory, including the sleep chamber and control room.

Electrophysiological measures were obtained using a 14-channel electroencephalograph (Nihon Kohden model 4314B), digitized, and stored on-line using the Microcomputer Quantitative Electrophysiology acquisition and anal-

Table 1.
Ratio of arousals to trials for individual subjects in Experiment 1.

Subject	Light Position	Distance to Pillow	Flash Rate	Ratio of Arousals SWS	Ratio of Arousals REM
1	F/B	180 cm	3 Hz	0/2	1/2
2	F/B	180 cm	3 Hz	0/0	4/4
3	F/B	180 cm	1 Hz	1/3	1/1
4	F/B	180 cm	1 Hz	0/2	1/2
5	F/B	180 cm	1 Hz	0/2	1/2
6	O/F	144 cm	1 Hz	0/2	1/2
7	O/F	75 cm	1 Hz	0/1	2/3

F/B = foot of bed; O/F = directly over face; SWS = slow wave sleep; REM = rapid eye movement sleep

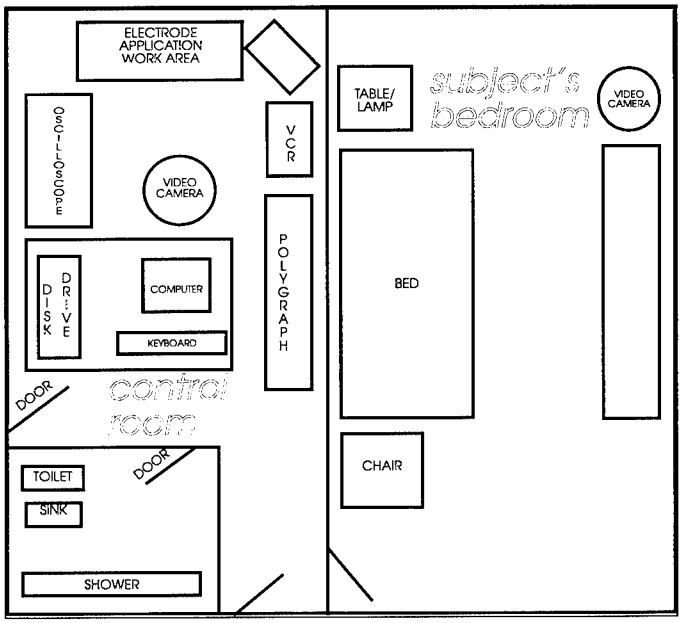

Figure 1.
Schematic diagram of behavioral testing laboratory, showing location of sleeper, experimenter, warning signal, and monitoring equipment.

ysis program (MQE). Data were archived using a Maximum Storage optical disk drive (model APX-5200) and an 8-channel FM tape recorder (Vetter, model D). The EEG data were also monitored using a 20 MHz oscilloscope (Hameg). A Sony Trinitron monitor with a Splitter/Inserter (RCA model TC147OA) and two RCA CCTV low illumination video cameras were used to monitor/videotape the subject and physiological measures simultaneously. These tapes can later be used to review sleeping positions during presentation of the flashes as well as the waking responses. An audiometer (Beltone) was used to screen hearing. A sound level meter (Bruel and Kjaer) was used to monitor the noise level in the subject's bedroom. Communication between the control room and the sleep room was maintained by an intercom system. The temperature of the sleep room was recorded at night and in the morning of a sleep session.

Procedures

Before taking part in the study, the subjects were asked to attend an orientation session where a demonstration of the sleeping session took place and consent forms were signed. The hearing test was then given. Subjects were asked to refrain from drinking caffeine after supper, drinking alcohol, or taking daytime naps on their scheduled day in the sleep laboratory.

Subjects were asked to arrive at the sleep laboratory about one hour before their normal bedtime to complete a pre-sleep questionnaire to assess daytime activities, and to have the electrodes attached. The criteria of Rechtschaffen and Kales (13) were used as a guideline for sleep recordings. One bipolar submental electromyographic (EMG) channel, and two horizontal electro-oculographic (EOG)—left and right outer canthus, each referred to A2—channels were used.

Silver disk electrodes filled with electrode cream were secured with Micropore surgical tape or collodion-soaked gauze (EEG placements) in order to record electrophysiological measures. Inter-electrode impedances were maintained below 5 K. A high-cut filter setting of 35 Hz and a time constant of 0.3 were used to process the EEG and EOG.

Once the subject had retired to bed, the researcher read the following instructions on the nature of the experiment and their laboratory duties:

> This is a study to test the effectiveness of visual fire-alerting devices during various stages of sleep. Once you are sleeping a flashing light will be presented. If this was an alerting device in your own home, assume that there could be smoke, flames, or heat in your room. Your only concern is evacuating your room as quickly as possible. Since these data will be extremely important in establishing guidelines for manufacturers of alerting devices for the deaf/hearing impaired, it is imperative that you get ready to evacuate as soon as you detect the signal. As soon as you detect the flashing signal, please sit up in bed and put your feet on the floor. Once this is complete you will be asked to lay back down to sleep again. Be careful not to pull the electrodes out since we will be monitoring and presenting the signals during different stages of sleep.

Subjects were also told that an award of 15 dollars would be offered to the person who, at the end of the study, had put her feet on the floor the fastest after the strobe had been flashed.

Once instructions had been given and the equipment calibrated, the sleep session began. To discern whether the light was being incorporated into the subject's dreams, when subjects were awakened by the strobe flash, they were asked what their last sleeping thoughts were. Each subject spent one night in the sleep lab. The location of the light was varied according to the results obtained with previous subjects. Including the first subject, who was tested to confirm that the equipment was operating correctly and to test the protocol, the first five subjects were tested with the light on the ceiling at the foot of the bed (i.e, in a typical position for a smoke detector). Next, one subject was tested with the light directly overhead on the ceiling. The final subject was tested with the light suspended over her face, since previous locations had been found to be ineffective.

The intensity of the strobe was increased in 30 sec increments until the subject awoke. If the subject failed to respond to the signal within 5 min, she was awakened via intercom, to avoid rewarding her for remaining asleep. Upon waking in the morning, subjects were asked to complete a post-sleep questionnaire to obtain a qualitative report of their night's sleep. Electrodes were removed and the subject was offered juice, coffee, and a snack, as well as the use of shower facilities.

Results

Table 1 summarizes the conditions and overall results of testing with individual subjects. The two columns on the right of the table report the ratio of successful wakings to trials, within SWS and REM sleep. It is clear that visual signals did not reliably wake subjects in any sleep stage, and that many subjects did not awaken even when the highest intensity levels were presented. It was therefore

decided that only the highest intensity levels available would be used during the second phase of this study and that all testing would occur with the light source directly over the face.

Experiment 2

Subjects

Thirteen women, age 18 and older, were recruited. None had a history of eye disease or epilepsy, and all were self-reported "good sleepers."

Procedure

Experiment 2 used the highest light intensity levels, presented close to the subject's pillow (75 cm) to ensure a bright and diffuse distribution of light on the face, regardless of sleeping position.

For each subject, one intensity of a strobe flash was selected for presentation once each during four test intervals: one early (before 3 a.m.) and one late (after 3 a.m.) stage of SWS and REM sleep, respectively. It was not always possible to do this, because in normal sleep cycles, SWS sleep tends to occur during the early part of the night and proportionally more time is spent in REM later in the night (**Table 2**). Signal intensity was initiated at 7.6 Lux on the first trial, and raised to 19.9 Lux on subsequent trials if the subject did not awake. The light was allowed to flash for an extended period of time (maximum of 5 min) on each trial, and the elapsed time to waking was noted. If waking had not occurred within 5 min, the light was considered ineffective for that trial.

On some trials, testing began with the 7.6 Lux; if the subject did not awaken within 5 min, the higher level stimulus was presented after a 2-min interval for a maximum allowable time of 5 min. If the subject remained asleep on the second trial, the intercom was used to awaken her, so as not to reward her for remaining asleep. This procedure provided a reasonable opportunity to wake the subject within an interval of time which would permit safe evacuation in the event of a real fire.

Behavioral data recorded included the date, subject number, night number, trial number, time, stage of sleep, tonic/phasic events, intensity of light, length of time for presentation of light, head/body position, and whether arousal had occurred. The time of sleep onset and thus test initiation was highly variable across subjects. Over 38[5] trials, the mean time between lights out and arousal varied between 18 and 263 min (mean = 89 min; SD = 66 min).

Results

Analysis: An arousal was recorded each time the subject awakened during light presentation. A nonarousal was recorded for each failure to respond to the light. The proportion of arousals was computed for each intensity level, and for each stage. **Table 2** summarizes test condi-

[5] Note that one subject had only two intervals averaged into the mean time between arousals (not three).

Table 2.
Summary of test conditions (sleep stage and light setting) and behavioral outcome for each trial in Experiment 2.

	Trial				
Subject	**1**	**2**	**3**	**4**	**5**
s1	SWS (8) FR	R/2 (8) FR	SWS (16) FR	*REM (16) FR	—
s2	SWS (8) FR	SWS (16) 0:10	REM (8) 2:07	—	—
s3	SWS (8) FR	REM (8) 1:39	SWS (16) FR	2 (8) FR	—
s4	SWS (8) FR	SWS (16) 0:13	REM (8) 0:10	REM (8) 0:14	—
s5	SWS (8) FR	SWS (16) FR	REM (8) FR	REM (16) FR	—
s6	SWS (8) FR	SWS (16) 0:07	REM (8) FR	REM (16) 3:38	—
s7	REM (8) 0:12	SWS (8/16) FR/1:06	REM (8/16) FR/3:26	—	—
s8	SWS (8/16) FR/FR	REM (8) 0:04	REM (8/16) FR/2:00	SWS (16) 4:00	—
s9	SWS (8/16) FR/FR	SWS (16) FR	REM (16) 0:05	REM (8/16) FR/0:04	—
s10	SWS (8/16) FR/FR	SWS (16) 0:10	*REM (8/16) FR/4:00	2 (16) FR	—
s11	SWS (8/16) FR/FR	REM (8) 0:02	2 (8/16) FR/2:59	REM (16) FR	—
s12	SWS (8/16) FR/FR	REM (8) 0:02	*REM (8) FR	SWS (16) FR	REM (8) 0:04
s13	SWS (8/16) FR/FR	REM (8/16) FR/FR	REM (16) FR	REM (16) FR	—

Note: Sleep stage is coded as SWS (slow wave sleep), REM (rapid eye movement sleep), 2 (Stage 2 sleep), or R/2 (mixed sleep stage) [* indicated where a stage change occurred during trial]; light level is setting of controller of light (8 μF or 16 μF) with 8/16 representing an advancement to higher intensity after a 2 min pause; behavioral outcome is coded as FR (failed to respond) or as the time from signal onset to arousal in minutes:seconds (maximum 5:00).

tions and behavioral outcome for each subject for each trial. In the table, "FR" indicates that the subject failed to respond within the 5 min time limit. Where times are given, the sleeper did awaken in the time indicated.

Probability of Arousal: Data were collapsed across subjects and trials, to determine the probability of waking from each sleep stage, as a function of light intensity. **Figure 2** displays how the cumulative probability of arousal increased overtime as the light flashed at a particular intensity level. Even over the full 5-min trial, *no* subject was awakened from SWS by the 7.6 Lux light, and waking occurred from SWS fewer than 30 percent of the trials with the 19.9 Lux level. Subjects were awakened from REM sleep approximately 50 percent of the time during the 5-min trial, with the overall proportion being almost identical for the two light intensities.

In all conditions, waking tended to occur soon after light onset or not at all: even at the highest intensity of light, a 30-fold increase in time for the light being on (from 15 sec to 5 min), only doubled the probability of arousal. However, the largest proportion of subjects failed to respond even after a full 5 min.

The proportions occurring with 2.5 min and 5 min of signal onset area is summarized in **Table 3.** Clearly, subjects did not wake consistently to the flashing signal at any sleep stage, or light intensity level. The overall probability of arousal within 2.5 min was only 27 percent. Doubling the time interval to 5 min increased the probability of waking by only 8 percent to a still unsatisfactory 35 percent, across conditions.

Sleep stage did affect probability of arousal, [$\chi^2(1,59) = 4.39$, $p < 0.05$] for the 2.5 min limit and [$\chi^2(1,59) = 5.26$, $p < 0.05$], indicating that arousal was more frequent from REM sleep than from SWS.

During REM sleep, there were no significant differences between the number of arousals at the two intensity levels presented (8 μF/16μF). During SWS however, arousal was significantly more frequent at the 16 μF intensity level [$\chi^2(1,30) = 5.74$, $p < 0.05$] and [$\chi^2(1,59) = 4.59$, $p < 0.05$] for the 5 min and 2.5 min criteria, respectively.

Intensity level did affect probability of arousal during SWS [$t(12) = 2.73$; $p < 0.05$; $m = 300.0$, $M_{16} = 201.6$]; there was no difference during REM sleep. This result may be due to the fact that many REM-16 trials were conducted following 5 min of REM-8 *during which waking did not occur:* thus, waking in the REM-16 condition may reflect some cumulative effect of the REM-16 condition with the preceding REM-8 condition. At the lowest intensity level sleep stage (SWS/REM) affected probability of arousal [$t(12) = -3.46$, $M_{REM} = 188$, $M_{SWS} = 300$].

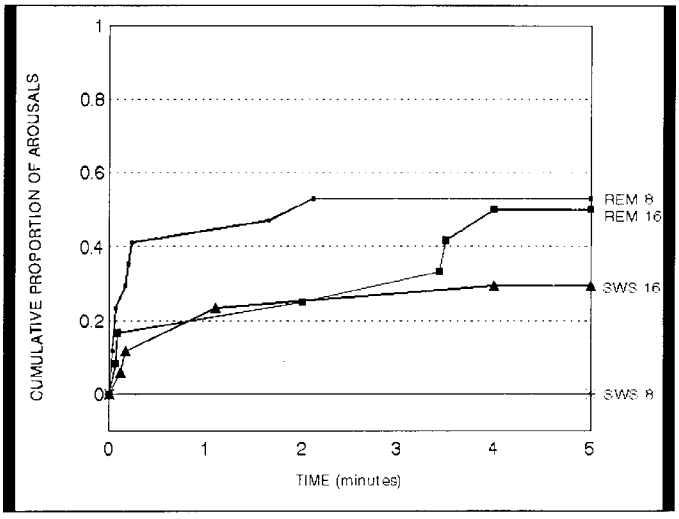

Figure 2.
Cumulative proportion of arousals as a function of warning signal type and duration. Data are averaged across all subjects and trials within the specified test condition (SWS 8 = slow-wave sleep with 8 μF light intensity; SWS 16 = slow-wave sleep with 16 μF light intensity; REM 8 = rapid-eye-movement sleep with 8 μF light intensity; REM 16 = rapid-eye-movement sleep with 16 μF light intensity).

Optical Testing

Procedure

The maximum candlepower in the main beam of the flashing signal lights was measured in a room that was completely dark. A photopically corrected photocell (SDC Corp. Model SD-444-31-12-173) was mounted on an ad-

Table 3.
Ratio of arousals to sleep trials at the 2.5 and 5 minute criterion as a function of light level, sleep stage (data for 13 subjects in Experiment 2).

		Stage of Sleep			
Control Setting	**Criterion**	**SWS**	**REM**	**Stage 2**	**Total**
8 μF	2.5 m	0/13	9/18	0/2	9/33
	5.0 m	0/13	9/18	0/2	9/33
16 μF	2.5 m	5/17	3/11	0/3	8/31
	5.0 m	6/17	5/11	2/3	13/31
Combined	2.5 m	5/30	12/29	0/5	17/64
	5.0 m	6/30	14/29	2/5	22/64

justable tripod at a distance from each light that was at least five times the largest dimension of the luminous opening of the light source under test. The photocell was connected to a Photodyne Digital Optical Power/Energy Meter Model 66XLA. The lights and the photocell were adjusted to the same height and oriented such that the cell was aimed directly at the main beam of the flashing light. The power to the light source under test was then turned on, the room lights were turned off, and measurements were made. The current energy generated by the light on the photocell was measured over a span of 10 flashes from the unit. This value was then divided by 10 to obtain the mean value per flash. Knowing the distance to the photocell, the area of the photocell, the current per lumen response rate of the photocell, and the average current generated by one flash, the instantaneous candlepower value of the flash can be calculated to yield the Instantaneous Candlepower. The effective candlepower to the human eye for a flash of very short duration is equivalent to five times the instantaneous value. The illumination created directly ahead of the light source can therefore be calculated for any desired distance from the light source.

Results

Table 4 summarizes the results of these measurements of the physical optical characteristics of the experimental light source and several representative visual smoke detectors. Two of these, the Gentex (GXS-20) and the Wheelock strobe light, exceed the ADA requirements; one, the 350-5 strobe, did not. (The following analysis will show that the test lights, being very close to the subjects, delivered more intense light to their eyes than would any presently available commercial light source.)

In the test position used in Experiment 2, the EEG strobe was lowered to 75 cm from the subject's head. This yielded a light level exceeding that which would have been achieved by any of the commercial smoke detector devices, when installed in a normal operating position. In this position, the light level at the subject's head was determined to be 19.9 Lux at the 16 μF setting and 7.6 Lux at the 8 μF setting. These values exceed those that would be obtained with normal installations, under even smoke-free conditions with the commercial devices.

DISCUSSION

This study developed and applied a procedure for testing visual alerting devices on sleeping humans. Unlike previous studies, the procedure provided a critically important control over the stage of sleep during testing. With this control, subjects did not wake consistently to the flashing light during the deepest stages of sleep. This result raises serious concerns about the safety of these devices during life-threatening situations.

In the normal operating position for smoke detector devices, on or near the ceiling at or beyond the foot of the

Table 4.
Summary of optical measurements for three commercially available smoke alarm systems and for the experimental light source used in behavioral testing.

Light Source	Wheelock (see LSC5263)	GXS-20	350-5	EEG Strobe (High setting) (16 μF)	EEG Strobe (2nd Highest setting) (8 μF)
Description of Optic	Xenon flash tube in parabolic reflector behind flat plastic lens	Xenon flash tube behind plastic hemispherical lens	Xenon flash tube behind plastic diffusing lens	Xenon flash tube in diffuse rectangular box with flat glass lens and protective metal mesh	Xenon flash tube in diffuse rectangular box with flat glass lens and protective metal mesh
Area of luminous opening (in m^2)	1.29×10^{-3}	8.067×10^{-4}	1.29×10^{-3}	4.034×10^{-3}	4.034×10^{-3}
Instantaneous Candlepower	31.38 cd	20.55 cd	0.386 cd	2.24 cd	0.860 cd
Effective Candlepower	156.9 cd	102.8 cd	1.93 cd	11.20 cd	4.30 cd
Illumination at 1m	156.9 Lux	102.8 Lux	1.9 Lux	11.2 Lux	4.3 Lux
Luminance	1.22×10^5 cd/m^2	1.27×10^5 cd/m^2	1496 cd/m^2	2776 cd/m^2	1066 cd/m^2

bed, the alerting device would be ≥ 3 m from the sleeper's face. At this distance, the commercially available smoke detector devices we measured would deliver a maximum of 17.3 Lux (Wheelock); 11.42 Lux (GXS-120); and 0.21 Lux (350-5) to the sleeper's face. In the testing position used in Experiment 2 (0.75 m from sleeper's face), the experimental light source used in our studies yielded 19.9 Lux (at the 16 μF setting) and 7.64 Lux (at the 8 μF setting). *The testing conditions therefore met or exceeded the levels provided by devices which are now widely available, and which meet current ADA specifications.*

In contrast to present results, measurements by UL suggest that the Gentex device provided higher light levels than the Wheelock device, whereas the measurements here show that the effective candle power of the Wheelock device was higher. The parabolic properties of the Wheelock device gave this strobe light the brightest rating because the photocell was so focused. Changes in measurement position (or in sleeping position), may interact with this strobe's directional properties and change the measured or perceived brightness. The directional relationship between the aperture of the strobe light and the position of the sleeper's head may affect effective light level in important ways, but it is unlikely that this factor is considered by consumers.

Deaf persons, who know of their dependence on visual alerting signals from home smoke detectors to wake them safely in the event of a fire, may demonstrate slightly *lower* waking thresholds due to the personal significance these signals have for them. However, it would be most imprudent to appeal to such "importance" factors to presume that the available visual alerting devices will wake such persons safely. In fact, since young university students with no health problems were used for this study, our results may be conservative. Several variables may *raise* the thresholds for waking beyond that seen here. These include sleep deprivation, fatigue, age, drugs, alcohol, exercise, chronic health problems, and medication, all of which might raise alerting thresholds even beyond those of the present study (5). The effectiveness of these devices must therefore be questioned, even under optimal circumstances.

In real-life situations, the presence of smoke would also obscure the visual signal. In view of this fact, the concern for safety generated by the results from this study is further enhanced. In practice, the effect of screening smoke should be factored into the intensity rating, since light obscuration will decrease effectiveness. UL reported that a 120 cd strobe would have to be increased to 195 cd (195/120 = 38 percent attenuation) to achieve, on average, an equivalent signal effect in the presence of smoke (5). Smoke obscuration increases with the height of the detector in a room, and smoke detectors are often located at or near the ceiling. Optimally, the detector would be located on the ceiling, to where the smoke is likely to rise, maximizing the sensitivity of the detector, while the strobe light should be located below this, to be closer to the sleeper to avoid the obscuring effects of smoke.

CONCLUSIONS

The purpose of this investigation was to evaluate the likelihood that a visual alerting device would be effective in waking a person from a "deep" stage of sleep. The results are clear: even under the favorable optical (smoke-free) conditions of the present study, the most intense of the devices presently offered for sale in Canada cannot be relied on to wake a sleeping person within 5 min. This is double the safe time recommended by the British fire safety code (1).

On the basis of these data, it is recommended that:

1. visual fire alerting devices should not be relied upon to alert sleeping persons;
2. other devices (vibrotactile/fans) should be tested under similar conditions to determine their suitability as fire alerting alternatives; and,
3. sleep stages should be monitored in subsequent evaluation of such alerting devices.

ACKNOWLEDGMENTS

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A SPECIAL REPORT

The VA-Cyberware lower limb prosthetics-orthotics optical laser digitizer

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Abstract—Characterization of the residual limbs and limb segments of patients for prosthesis and orthosis design has principally been a subjective process, highly dependent upon the skill, level of training, and experience of the prosthetist/orthotist involved. Even with the application of computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies in prosthetics and orthotics, residual limb/limb segment characterization has remained substantially subjective and dependent upon prosthetist/orthotist skill, training, and experience. To eliminate the variations and errors that frequently occur because of this dependence, and to further quantify the patient measurement process, rehabilitation engineering researchers at the New York Department of Veterans Affairs Medical Center developed an optical laser digitizer for quantitative characterization of patients' residual limbs'/limb segments' spatial geometry and surface topography. The optical digitizer developed is described, and results of laboratory and clinical tests with the digitizer are presented. Examples showing the capability of the digitizer to accurately, rapidly, repeatably, and consistently capture the contours over the entire surfaces of the residual limbs of patients with below-knee (BK) and above-knee (AK) amputation, the lower limbs of orthotics patients, and the feet and ankles of pedorthics patients, are given. In addition, results of a comparative clinical study of optical digitization and standard prosthetics CAD plaster wrap cast electromechanical digitization of the residual limbs of subjects with BK and AK amputation are presented. The enhanced accuracy, repeatability, and consistency afforded by optical digitization are shown. Finally, areas for refinement of the optical digitizer's design, identified in the project's laboratory and clinical tests, are discussed.

Key words: *AFMA, anthropometry, CAD/CAM, computer-aided design, limb (segment) measurement, optical laser digitizer, orthotics, prosthetics, residual limb measurement, three-dimensional spatial digitization.*

INTRODUCTION

Research which began in the early 1980s in prosthetics computer-aided design and computer-aided manufacturing (CAD/CAM) has produced an extensive armamentarium of tools, enabling prosthetists to design and manufacture prosthetic sockets with precisely controlled shapes and dimensions. However, significant portions of the prosthetics CAD/CAM process still remain largely subjective and need to be further quantified and improved. Almost all current prosthetics CAD/CAM systems acquire and input patient residual limb measurement data by (opto-)electromechanical digitization of plaster wrap casts. Either unmodified or modified residual limb plaster wrap casts may be used. When modified plaster wrap casts are used, the casts and measurements for CAD system input are subject to inter- and intraprosthetist variations and errors just as in conventional prosthetics practice. In two separate studies, variations of up to 10 percent in cast circumferential measurements, 21 percent in cast cross-sectional areas, and 33 percent in cast segmental volumes were observed among different prosthetists measuring and casting the same patient employing conventional prosthetics techniques. Similarly, as

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much as 8 percent, 17 percent, and 27 percent variations, respectively, were observed for a single prosthetist measuring and casting the same patient multiple times[1] (1). When unmodified plaster wrap casts were taken, digitized, and used for CAD system input, interprosthetist variations up to 6 percent in circumferential dimensions, 10 percent in cross-sectional area dimensions, and 22 percent in cast segmental volumes were observed. Although less than those observed with modified casts, these variations are still quite significant.

Because nearly all current prosthetics CAD (opto-)electromechanical digitizers record three or fewer reference marks, the CAD prosthetist must estimate the location, orientation, size, and shape of key residual limb anatomical structures, tissue anomalies, stress tolerant and intolerant regions, etc. In conventional prosthetics practice, this information is marked on the surface of the patient's limb, transferred to the plaster cast, and then to the positive plaster model for subsequent use in socket design. Errors can be, and frequently are, introduced when the surface landmarks are displaced with tissue movement during the casting process. Although limited in accuracy, the information the conventional prosthetist has regarding the location, shape, size, and topographies of residual limb anatomical structures, tissue anomalies, and stress tolerant and intolerant regions is, nevertheless, more than the CAD prosthetist has. The CAD prosthetist currently must estimate this information, based on recollections of the examination of the patient, and his or her prosthetics knowledge and experience; or, he or she must depend on the compliance of the patient to the "statistical average values" implemented in CAD system socket design templates, and also upon the accuracy of the CAD system in locating and scaling the respective template modification regions.

During the socket design process, the CAD prosthetist is able to more precisely and accurately control socket model geometries, dimensions, areas, and volumes, than is the conventional prosthetist building up and cutting away regions on a positive plaster model. But the CAD prosthetist currently has less information with which "to build" a computerized socket model than does the conventional prosthetist. This situation is further aggravated by the wide range of variations that exist in the anatomies and residual limb tissue mechanical properties of patients. As found in the Department of Veterans Affairs (VA) Rehabilitation Research and Development (Rehab R&D) Service National Automated Fabrication of Mobility Aids (AFMA) Study, when default template modification regions, appropriately scaled to match residual limb size but otherwise fixed, were used, considerable additional custom modification was usually required before a successful socket design, affording good fit, comfort, and function, was achieved. In the National AFMA Study, 67 percent of the test subjects with below-knee (BK) amputation required additional custom modification in the socket template patellar bar region; 61 percent of the subjects required additional custom modifications in the anterodistal tibial region; 59 percent in the anterolateral tibial region; 52 percent in the anteromedial tibial shaft region; 52 percent in the popliteal depression region; 52 percent in the medial femoral and tibial condyle region; 50 percent in the lateral femoral and tibial condyle region; 49 percent in the fibular head region (especially posteriorly); 46 percent in the fibular end region; 37 percent in the region over the medial tibial condylar flare (especially posteriorly near the insertion of the medial hamstring tendon); 37 percent in the popliteal trim line region near the hamstring tendons; and 34 percent required additional modifications over the fibular shaft (2).

An improvement in CAD system capabilities and performance was made when modification region linking to specific residual limb landmarks (as performed routinely in conventional prosthetics practice) was introduced in the VA-Seattle ShapeMaker CAD System. However, modification region linking to a limited number of landmarks, as the two locations currently implemented in ShapeMaker, has proven to be insufficient in many cases. For the low angular and axial digitizer resolutions and the three or fewer residual limb landmarks currently input for use in standard prosthetics CAD/CAM systems (**Figures 1** and **2**), appreciable deviations in template modification region location, orientation, and size still frequently occur. In a sample of 14 test subjects with BK amputation, variations in modification region location as large as 3.8 cm linearly on the surface and angularly as large as 22° occurred upon application of the ShapeMaker BK PTB socket design template to digitized residual limb measurements with only the three anatomical reference landmarks currently available (**Figure 3a**). Similarly, variations as large as 11 cm linearly on the surface and angularly as large as 183° were found to occur in modification region location with the ShapeMaker AK IC socket design template for 14 test subjects with above-knee (AK) amputation (**Figure 3b**).

[1] *Residual limb geometric characterization: Comparison of prosthetics CAD/CAM optical digitization, electromechanical digitization, and conventional prosthetics casting techniques,* by V.L. Houston, C.P. Mason, K.P. LaBlanc, et al., is in preparation.

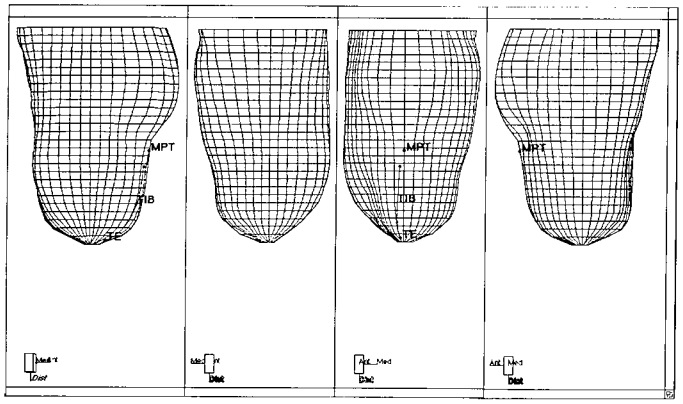

Figure 1.
Lateral, posterior, anterior, and medial views of the electromechanically digitized unmodified plaster wrap cast of the right residual limb of a person with BK amputation are shown input into the VA-Seattle ShapeMaker CAD System. The wire frame residual limb measurement model is shown at the 10° cross-sectional angular increment and 6.35 axial increment resolutions output by most prosthetics CAD/CAM (opto-)electromechanical digitizers. The anatomical landmarks most commonly registered—the mid-patellar tendon (MPT), the tibial shaft (TIB), and the tibial end (TE)—are also shown.

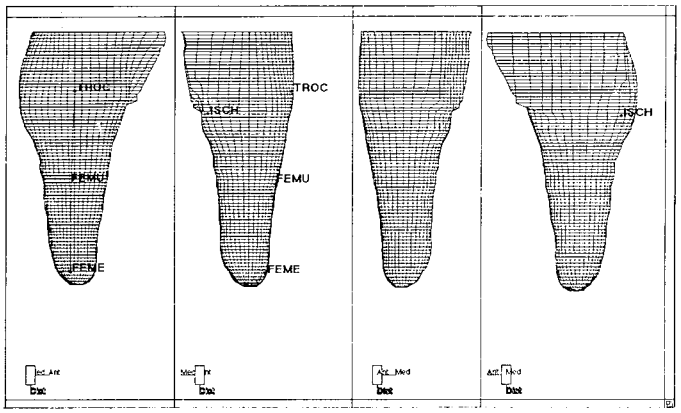

Figure 2.
Lateral, posterior, anterior, and medial views of the electromechanically digitized unmodified plaster wrap cast of the right residual limb of a person with AK amputation are shown input into the VA-Seattle ShapeMaker CAD System. The wire frame residual limb measurement model is shown at the 10° cross-sectional angular increment and 6.35 axial increment resolutions output by most prosthetics CAD/CAM (opto-)electromechanical digitizers. The anatomical landmarks most commonly registered—the greater trochanter (TROC), femoral shaft (FEMU), femoral end (FEME), and ischium (ISCH)—are also shown.

However, if as demonstrated in our investigations, CAD system template modification regions are linked to multi-

CAD PTB Socket Design Template Location of Fibular Head Modification. Region Vs. BK Amputee Residual Limb Fibular Head Location.

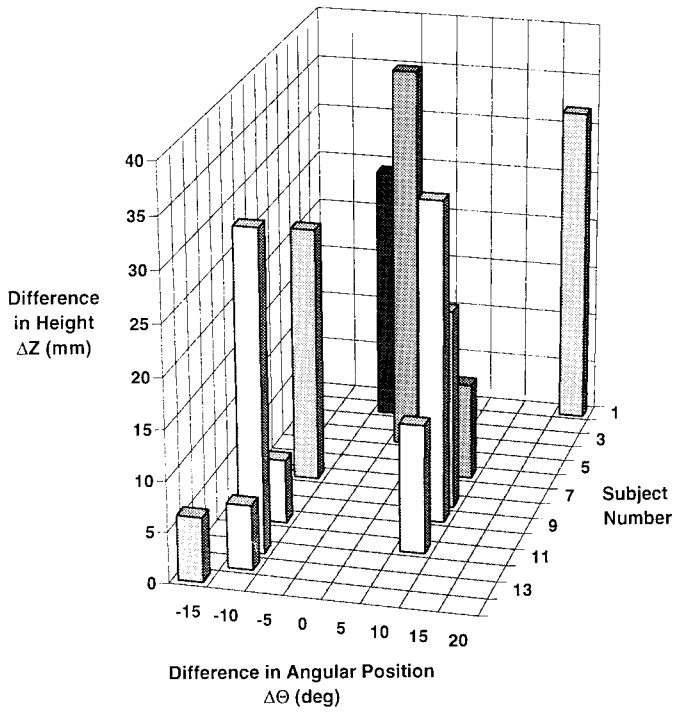

Figure 3a.
Prosthetics CAD system socket design template modification region location errors from insufficient residual limb landmark information. Differences in the optically measured location of the residual limb fibular head apex versus the position of the ShapeMaker PTB socket design template fibular head modification region apex for 14 subjects with BK amputation are shown.

ple anatomical residual limb landmarks, identified during patient examination, preserved through residual limb digitization, and registered in the measurement file input into the CAD system, then variations in socket modification region location, orientation, and size become minimal. The principal issue for successful socket design is then the establishment of the magnitudes and topographies of the modification regions. The values for these variables required for achievement of successful socket fit, comfort, and function depend upon the residual limb tissue morphology, geometry, and tissue biomechanical properties of the individual patient. The skilled conventional prosthetist obtains subjective information regarding these variables during the casting process, as he or she molds the residual limb tissues of the patient. Only if the CAD prosthetist makes and uses a modified residual limb cast does he or she have

CAD AK IC Socket Design Template Location of Quadriceps Modification. Region Vs. AK Amputee Residual Limb Quadriceps Location.

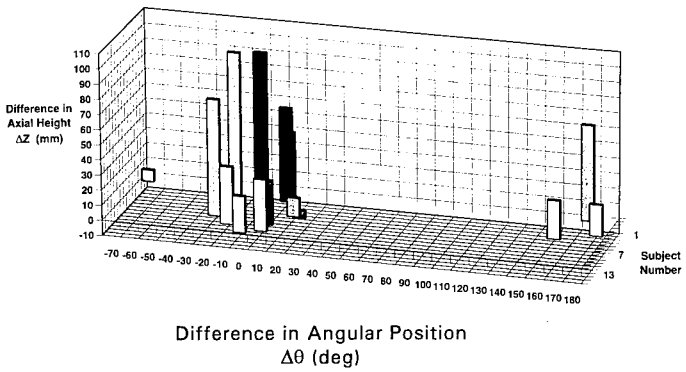

Figure 3b.
Prosthetics CAD system socket design template modification region location errors from insufficient residual limb landmark information. Differences in the spatial location of the residual limb quadriceps (mediolateral) midpoint at ischial level versus the position of the ShapeMaker AK IC socket design template quadriceps depression modification region focus for 14 subjects with AK amputation, are shown as measured (i) optically on the residual limbs of the test subjects, and (ii) in the VA-Seattle ShapeMaker CAD System following application of the respective socket design templates to the subjects' electromechanically digitized undistorted plaster wrap cast measurements.

similar information. Quantitative characterization of these parameters for input into prosthetics CAD systems is needed. This is currently under investigation by NY VAMC Rehab Engineering researchers.

Even with these limitations, as shown in the National AFMA Study (2), CAD/CAM technologies improved the mean quality of, and expedited the delivery of, patient prosthetics care. CAD/CAM technologies, on the average, reduced the time required for residual limb measurement acquisition/socket design model preparation and socket design and manufacture. In conventional prosthetics practice, 1.5 hr or more are required for BK amputee residual limb casting, and subsequent cast pouring, plaster setting, and plaster wrap stripping in preparation of a positive plaster model for socket design. In current prosthetics CAD, there is a savings of approximately 40 minutes for BK amputee residual limb measurement acquisition, (opto-)electromechanical digitization, and CAD system residual limb measurement input. (The time savings in residual limb measurement acquisition, digitization, and CAD model input may be reduced, however, for large patients with AK amputation, if resolutions higher than the current standard prosthetics CAD 10° angular and 6.35 cm longitudinal resolutions are used during (opto-)electromechanical digitization of the plaster wrap cast.) If little or no custom modification is required, CAD socket design can be performed in approximately 2 to 5 min, and CAM of a corresponding positive plaster socket model requires approximately 15 to 20 min. Automated CAM thermoforming of a socket requires approximately 30 min (15 min to heat the plastic preform, 5 min to form the socket, 5 min for the plastic to cool to ambient temperature, and approximately 5 min to remove the positive plaster model). Conventional prosthetics procedures require 30–60 min, at least, for design of a socket through modification of a positive plaster residual limb cast, and a minimum of 1 to 2 hr to laminate a socket over the resulting positive model. Thus, 45 min to 2 hr, or more, in time savings can be achieved in socket design and manufacture through application of CAD/CAM technologies. To ensure that these time savings are realized, and to ensure that the best fitting, most comfortable, functional, and cosmetic prostheses possible are provided to patients, complete and accurate quantitative information characterizing residual limbs of patients for CAD system input is needed.

To more accurately, consistently, and reliably characterize the spatial geometry and surface topography of patients' residual limbs and limb segments—and to significantly reduce measurement acquisition and CAD socket/orthosis design model input times still further—in 1991, we established specifications and a design for a prosthetics-orthotics optical laser digitizer capable of directly scanning the residual limbs and limb segments of patients, and detecting and preserving the locations of multiple landmarks in 5 sec or less (3,4). In 1992, a prototype digitizer was designed and manufactured under VA Rehab R&D sponsorship by Cyberware Laboratory, Inc. of Monterey, CA. In 1993, software was developed for the VA-Cyberware prototype digitizer for control, data acquisition, image generation, image processing, and measurement file format conversion for prosthetics-orthotics-pedorthics CAD/ CAM system input. A series of laboratory and clinical tests were conducted to determine the performance capabilities and limitations of the prototype digitizer. This paper reports the results to date of this work.

METHOD

In its present design, the VA-Cyberware prosthetics-orthotics optical laser digitizer consists of two scan heads

(an anterior master head and a posterior slave head) mounted on vertical uprights on synchronized, stepper motor driven, elevation control assemblies (**Figure 4**). Each scan head contains a 10 mw near-infrared laser, two charge coupled device (CCD) cameras, prisms, mirrors, and associated optics. To digitize a residual limb or limb segment of a patient, the patient is positioned in the digitizer with the limb properly anatomically aligned and centered "as best as possible" in the digitizer's scannable spatial envelope. The scan heads are elevated under computer control to a position slightly above the segment of the limb to be scanned, and then are synchronously driven down the vertical uprights. As the scan heads travel down the uprights, horizontal cross sections of the patient's limb are sequentially digitized. Samples are taken with resolutions of $\leq$ 1.0 mm radially (from the cameras) in 460 angular increments (from the cameras). The data are then parsed and processed to yield 128 uniformly spaced samples around each cross section of the patient's limb. The incremental spacing between digitized cross sections is determined by the speed at which the scan heads are driven down the vertical uprights. Speeds yielding longitudinal incremental spacings of 1.5–6.35 mm, to an accuracy of $< \pm$ 0.1mm, can be selected by the digitizer operator. With selection of an incremental axial spacing of 3.1 mm, a scan head velocity of 9 cm/sec is achieved, enabling 22,250 points over a 15-cm-long residual limb of a subject with BK amputation to be digitized in approximately 2 sec. Similarly, approximately 3.5 sec are required to digitize 47,500 points along a 32-cm-long residual limb of a patient with AK amputation, and approximately 10 sec are required to digitize 141,000 points over the 95 cm length of the lower limb of an orthotics patient, from the crest of his or her pelvic ilium to the plantar aspect of his or her foot.

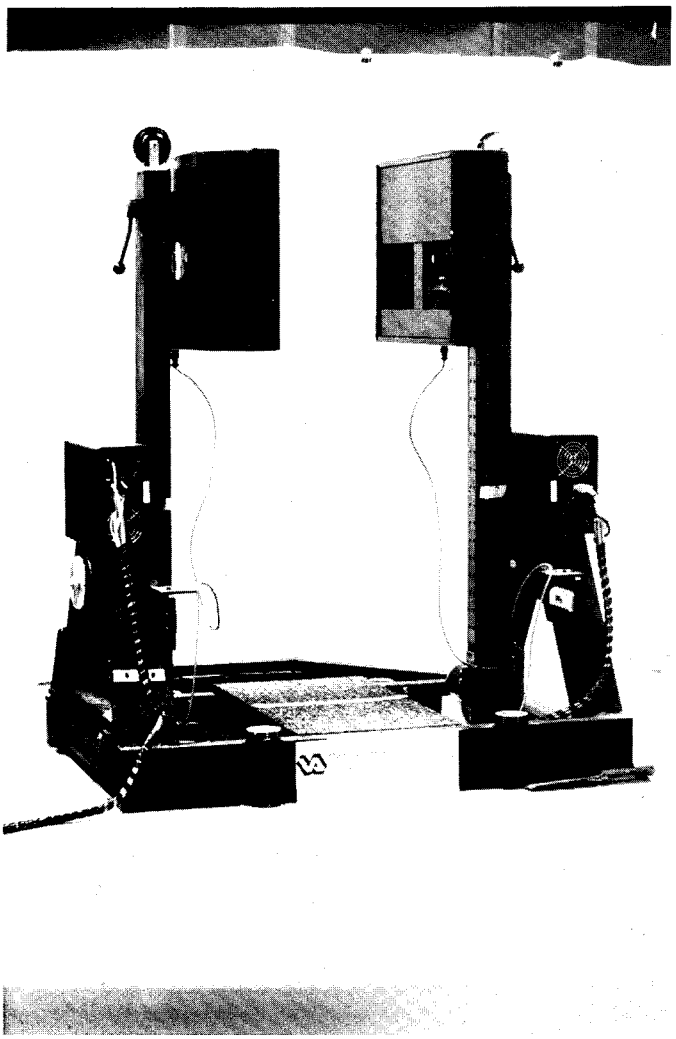

Figure 4.
The VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer. The master and slave scan heads, containing the lasers, optical elements, and charge coupled device (CCD) cameras, are shown at their proximal limits at the top of the digitizer's vertical uprights. The stepper motors actuating scan head movement may be seen at the base of the vertical uprights. The scan head electronic control circuitry is housed in the enclosures in the digitizer frame next to the vertical uprights. For digitization, the patient is positioned between the vertical uprights, centered in the digitizer's scannable envelope. The scan heads are raised proximal to the patient's limb and are synchronously driven down the vertical uprights, incrementally sampling horizontal cross sections over the length of the patient's limb/limb segment.

During digitization, light emitted from the laser diode in each scan head is optically split by mirrors in the scan head and refracted into plane segments of coherent, near-infrared light, transmitted into the right and left sides of each head. The resulting plane segments of light are then redirected with mirrors and projected at $\pm$ 41.5°, respectively, from the scan head normal onto the right and left sides of the patient's limb. The right and left plane segments from each scan head overlap in the center of the scannable field, so that together they form a continuous horizontal plane of laser light, incident approximately 200° around the limb of a patient (**Figure 5**). The light from the anterior and posterior scan heads also is designed to overlap by approximately 10° on the medial and lateral sides of a patient's limb, so the limb is completely encircled. The lasers and cameras in the anterior and posterior scan heads are synchronously gated on and off 180° out of temporal phase to avoid interference with each other. As seen in **Figures 5** and **6**, the laser light specularly reflected from the anterior and posterior halves of a patient's limb follows paths similar to that traversed by the laser source light,

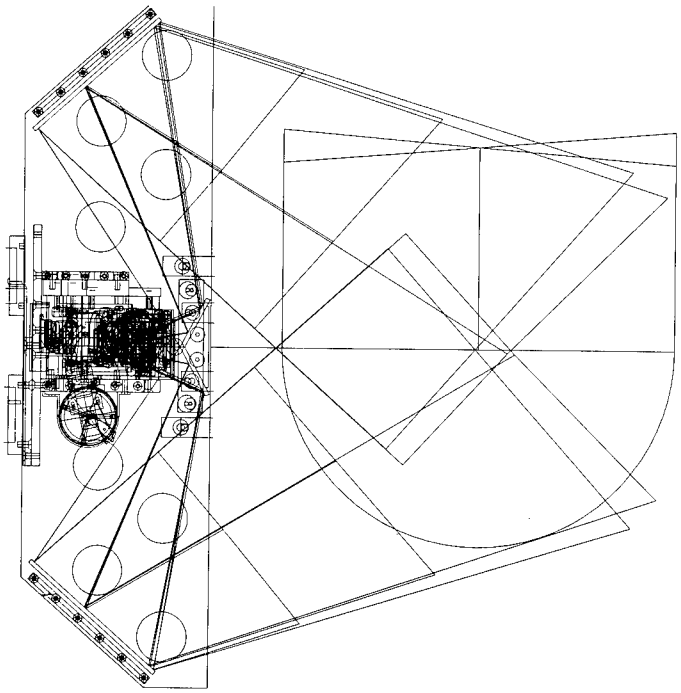

Figure 5.
Schematic diagram of a VA-Cyberware Optical Laser Digitizer scan head. The scan head's field of illumination is shown defined by the boundary of the paths of laser light emitted, split, defracted, and redirected in the right and left sectors of the scan head at ± 41.5° to the normal. The scan head's cameras' fields of view are shown defined by the lines of sight that map into the cameras' outermost pixels. As shown, the scan head's laser's field of illumination is larger and contains the scan head's cameras' fields of view. The "D"-shaped target depicted being scanned, is a cross section of an NY VAMC test phantom.

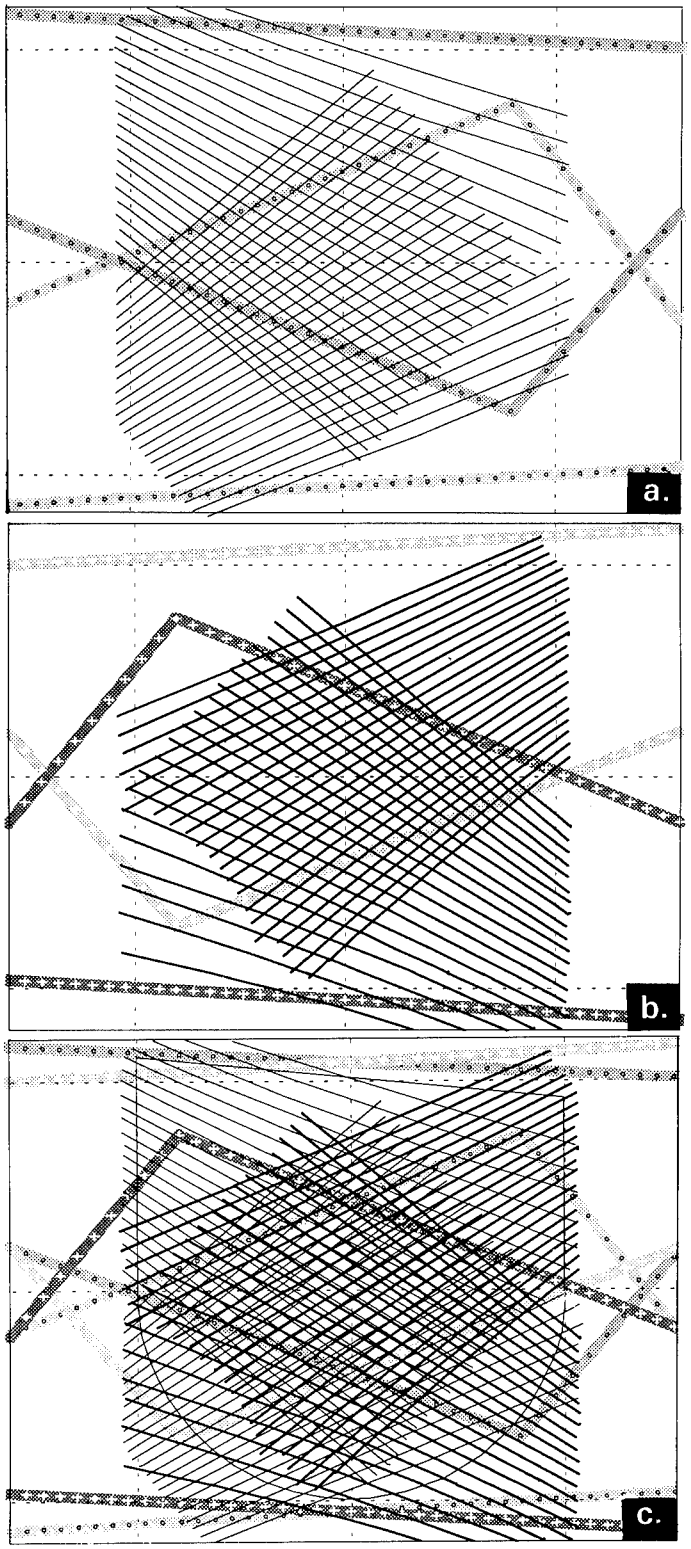

Figure 6.
The empirically measured fields of view of the present prototype VA-Cyberware Optical Laser Digitizer scan heads. The "lines of sight" of the scan heads' cameras' pixels are shown for every fifth pixel for (a) the slave scan head; (b) the master scan head; and (c) the composite fields of view of the master and slave scan heads. The broad, light gray lines define the theoretically predicted boundaries of the scan heads' cameras' fields of view. The nonlinearities, nonsymmetry, and nonuniformity of coverage of the fields of view by the cameras' pixels' lines of sight, together with the differences in these characteristics between the master and slave scan heads, are apparent. The increased inter-pixel line of sight spacing near the medial and lateral borders of the scan heads' cameras' fields of view is also apparent in (c).

except that when it enters the scan head and reaches the vicinity of the laser, the returning reflected light is focused onto the right or left half, respectively, of the given CCD arrays of the scan heads' cameras. The two cameras in each scan head are mounted directly above and directly below the laser, so that they view the reflected cross-sectional

images of the limb from 15° above and from 15° below the plane of laser light incident on the limb. With this design, the optical digitizer is functionally equivalent to a digitizer with four lasers and eight cameras.

The output signals from the upper and lower cameras in each scan head are averaged when both signals are present, or passed through if only one signal is present. This enables contours on a patient's limb hidden from one camera's view, but seen by the other camera, to be captured and preserved. The resultant output signals from the cameras of each scan head are also passed through empirical correction filters to compensate for nonlinearities in the respective scan heads' optics. The resulting corrected output signals, with the relative positional information (CCD array row and column addresses) of the cameras' illuminated pixels, are subsequently mapped into (x,y,z)-coordinates via a triangulation algorithm relating camera pixel equivalent optical origin and height to the corresponding reflecting limb surface's relative spatial coordinates. During postprocessing of the measurements, the pixel image data obtained from the digitizer scan heads' cameras are displayed, and the digitizer operator is permitted to interactively select longitudinal and latitudinal boundaries inside of which the data are saved, and outside of which the data are deemed extraneous and are discarded. This considerably reduces the optical digitizer measurement file size and subsequent data processing time. After the operator has selected the portion of the measurement data to be saved, the data are further filtered to remove high frequency optical and electrical noise and any outliers. Also, where the measurements in the right and left, anterior and posterior quadrants overlap, a moving average least mean square fit of the data is performed to derive a continuous, uniformly angularly spaced, estimate of the respective limb surface cross-sectional contours.

To identify landmarks, surface markers similar to the markers used in computer-aided tomography (CAT) and magnetic resonance imaging (MRI) are pre-positioned at the surface locations of key anatomical features on the patient's limb. The markers are detected during scanning and identified and registered during postprocessing of the measurements. Unlike the CT or MRI reference markers, however, the prosthetics-orthotics optical markers are color encoded (white and black), so they can be detected from measurements of the digitizer cameras' RGB (gray scale) output intensities. The detected markers' centroids are calculated and mapped via optical triangulation to their corresponding scan field spatial coordinates. The measurements are then compiled in a file, together with the anatomical landmark information, in a format selected by the digitizer operator. The resulting measurement file is then stored in the given patient's subdirectory on the digitizer computer, and subsequently transmitted to a designated CAD system for prosthesis, orthosis, or pedorthosis design.

RESULTS

Laboratory Tests

Laboratory tests have shown the VA-Cyberware Optical Laser Digitizer prototype to be capable of accurately digitizing the surface contours of three-dimensional objects lying inside a 28-cm-deep × 30-cm-wide × 95-cm-high spatial envelope. Tests, using calibrated "phantoms" similar to those employed in testing and calibration of radiological CAT and MRI scanners, have shown the digitizer to be capable of resolving contours on the surface of a scanned object to $< \pm 0.5$ mm mediolaterally along the y-axis near the center of the horizontal scan field and to ± 1.5 mm mediolaterally near the scan field periphery; to $< \pm 1.0$ mm anteroposteriorly along the x-axis near the center of the horizontal scan field and to ± 3.0 mm anteroposteriorly near its periphery; and, operating at its minimal vertical scanning speed, to $< \pm 0.5$ mm in height along the z-axis. Laboratory tests have further shown that the digitizer has a repeatability from scan-to-scan of $< \pm 0.5$ mm relative to a fixed spatial reference frame. Over a 6-mo period, the digitizer has also been shown to have a consistency from day-to-day between scans of $< \pm 0.5$ mm (provided the digitizer's optics are kept clean, the digitizer is not moved, and the scan heads are not pivoted so that the alignment of the optical elements is not altered—which necessitates recalibration and calculation of new compensation coefficients. It should be noted that cleaning the digitizer's optical elements, unlike inadvertant displacement, restores the digitizer's sensitivity without the need for recalibration.)

Clinical Tests

Clinical tests have shown the optical digitizer to be an effective, accurate, consistent, and expeditious tool for quantitative characterization of the spatial geometry and surface topography of the residual limbs of persons with amputation, and the limb segments of orthotics and pedorthics patients. **Figure 7** shows the residual limb of a test subject with BK amputation being scanned. **Figure 8** shows the distal view of the composite pixel images acquired from the digitizer scan heads' cameras. The pixel

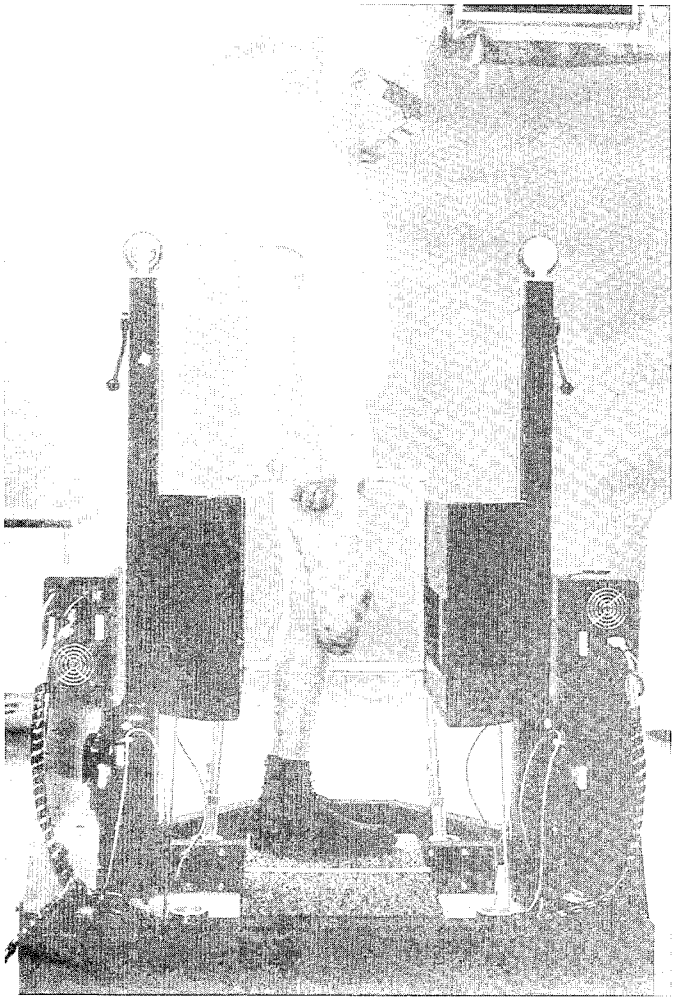

Figure 7.
Clinical testing of the VA-Cyberware Optical Laser Digitizer in measurement of the spatial geometry and surface topography of the residual limb of a test subject with right BK amputation.

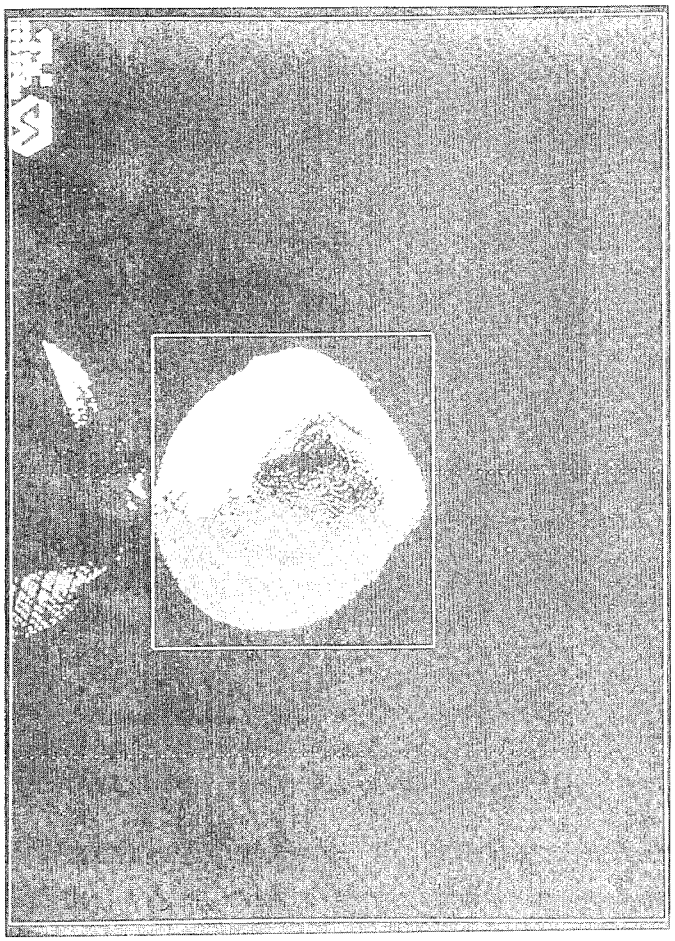

Figure 8.
Distal view (from the floor up) of the optical digitizer's master and slave scan heads' composite pixel measurements of the residual limb of the test subject with right BK amputation shown in Figure 7. The scan heads' cameras' pixel measurement data are shown mapped into their corresponding scan field (x,y,z)-spatial coordinates, but otherwise unprocessed. On the medial and lateral aspects of the residual limb, where the illuminated pixel densities are higher, is where the measurement data from the master and the slave scan heads' cameras overlap. The white lines boxed around the subject's residual limb are the scan postprocessing "data extraction windows," interactively defined by the digitizer operator, for selection of the pertinent scan data to be saved and the extraneous scan data to be discarded.

image data are shown mapped to their relative spatial coordinates via the optical triangulation transformation, but otherwise unprocessed. Data sorting boundaries for extraction of pertinent residual limb data may be seen in **Figure 8.** The light gray dots in this figure are the data acquired by the anterior scan head cameras, and the darker dots are the data acquired by the posterior scan head cameras. The data from the anterior and posterior scan heads' cameras overlap where the illuminated pixel densities are greater on the medial and lateral sides of the residual limb. **Figure 9** shows the lateral, posterior, anterior, and medial views of the residual limb measurement data, after they have been processed, formatted, and input into the ShapeMaker CAD System for prosthetic socket design.

Figure 10 shows digitization of the residual limb of a test subject with AK amputation. Anterior and distal views of the resulting composite pixel images from the digitizer's scan heads' cameras are shown in **Figure 11.** The ability of the digitizer "to see" between patients' legs, completely capturing residual limb cross-sectional contours, is illustrated in **Figure 11b.** The regions with increased pixel density on the medial and lateral aspects of

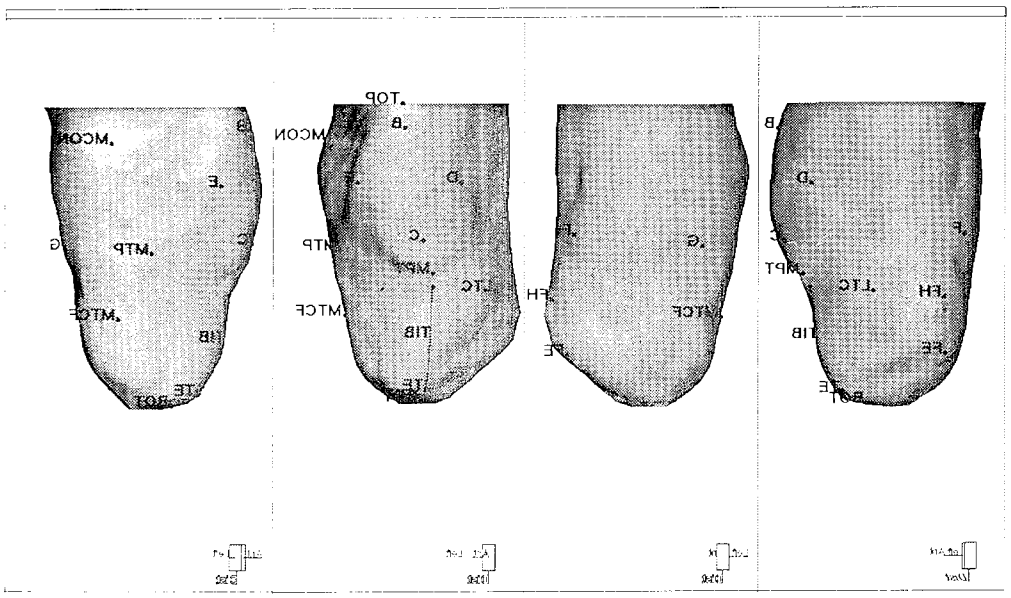

Figure 9.
Lateral, posterior, anterior, and medial views of the residual limb measurement data from the optical scan of the test subject with right BK amputation in Figure 8 are shown input into the VA-Seattle ShapeMaker CAD System for prosthetic socket design.

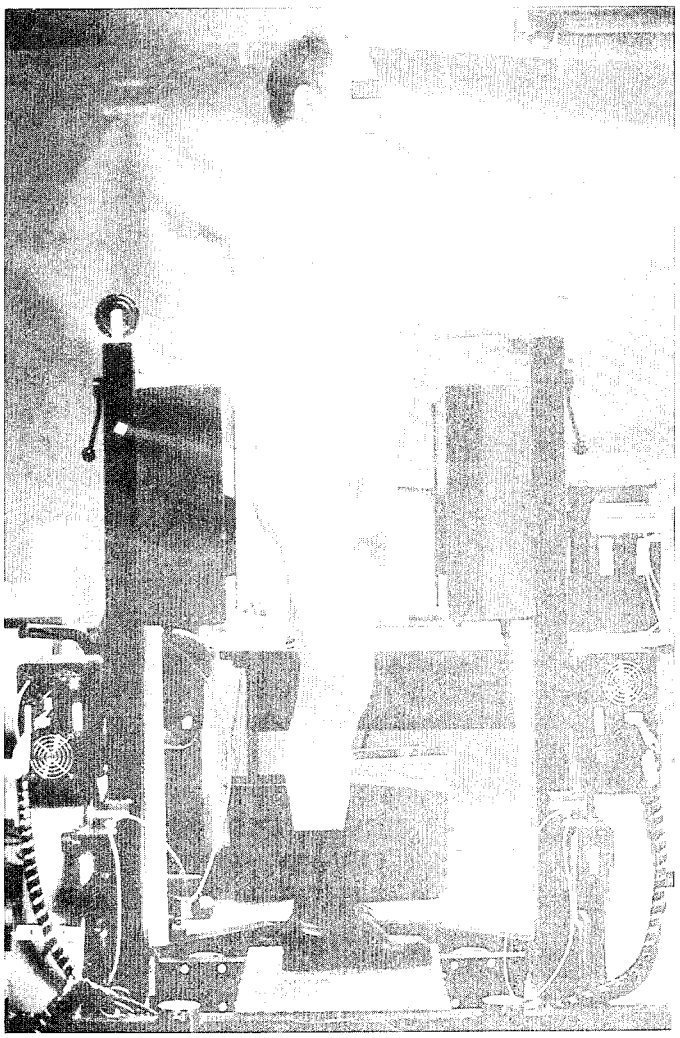

Figure 10.
Clinical application of the VA-Cyberware Optical Laser Digitizer in measurement of the spatial geometry and surface topography of the residual limb of a test subject with right AK amputation.

the limb are where data from the anterior and posterior scan heads' cameras overlap. **Figure 12** shows lateral, posterior, anterior, and medial views of the resulting residual limb measurement data after they have been processed, formatted, and input into the ShapeMaker CAD System for socket design.

Figure 13 shows digitization of the lower limb of a neuromuscularly impaired orthotics patient. Posterior and distal views of the resulting composite pixel images from the digitizer scan heads' cameras are shown in **Figure 14.** The ability of the digitizer to characterize the spatial geometry and surface topography of the lower limbs of orthotics patients, from the crests of their ilia to the plantar aspect of their feet, is demonstrated in **Figure 14a.** The digitizer's ability to see between the legs of orthotics patients capturing femoral and tibial limb segment contours is evident in the distal view shown in **Figure 14b. Figure 15** shows lateral, posterior, anterior, and medial views of the digitizer measurement data, after the data have been processed, formatted, and input into the ShapeMaker CAD System for knee-ankle-foot orthosis (KAFO) design. During scanning, if a patient's limb is malaligned (e.g., in excessive recurvatum, varus, or valgus), then either 1) the orthotist or physician can properly align the respective limb segments, holding them in position during digitization, and

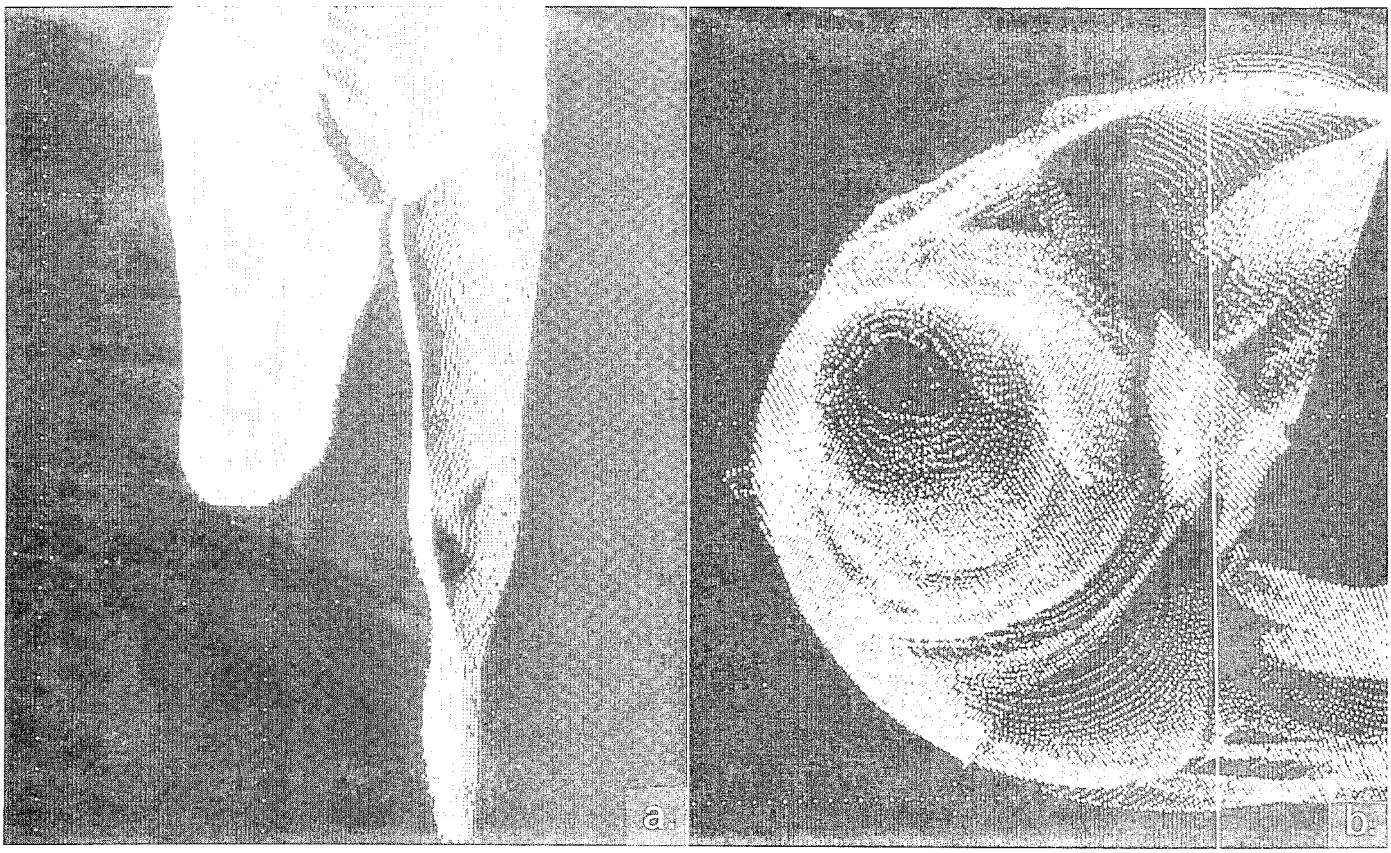

Figure 11.
The optical digitizer cameras' pixel measurement data from the scan of the test subject with right AK amputation in Figure 10 are shown. (a) The slave scan head's pixel measurement data of the anterior surface of the subject's residual limb; and (b) the distal view (from the floor up) of the master and slave scan heads' composite pixel measurement data are shown. The pixel measurement data have been mapped into their corresponding scan field (x,y,z)-spatial coordinates, but are otherwise unprocessed. Where the illuminated pixel densities are greater, on the medial and lateral aspects of the subject's residual limb in the distal view (b), is where the measurement data from the master and the slave scan heads' cameras overlap. The digitizer's ability to capture contours over the entire surface of the subject's residual limb, including over the perineal and lateral aspects of the limb, is clearly shown.

subsequently editing out any artifacts that ensue (e.g., an orthotist's fingers encroaching in the measurements); or 2) the orthotist can select common reference frame coordinates, apply appropriate optical reference markers on each limb segment, scan each limb segment separately, and then mutually align and "zipper" the resulting limb segment measurement sets together using specialized digitizer application software. The former method is less complex and usually found to be easier.

Figure 16 shows digitization of the foot and ankle of a pedorthics patient: the horizontal plane of laser light incident on a cross section of the foot of the subject during digitization is evident. As in orthotics applications, pedorthics patients' feet/ankles that are malaligned can be corrected (to the extent possible) during the digitization process, and any resulting artifacts edited out when the data are imported into the CAD system for subsequent pedorthosis design.

Detection and identification of residual limb (limb segment) landmarks are illustrated in **Figure 17.** High contrast red, white, and black optical markers were pre-positioned at the femoral adductor tubercle, medial femoral epicondyle, lateral femoral epicondyle, mid-patellar tendon, medial tibial condylar flare, fibular head, fibular end, and mid-tibial shaft crest of a test subject with BK amputation. The subject's residual limb was then scanned. The resulting output intensities from the digitizer's cameras were measured and filtered. Bandpass filtering the digitizer camera output intensities at the marker intensity variation frequencies attenuates the "background" portion of the data produced by light reflected from the surface of the residual limb, and "passes," unchanged, the portion of the

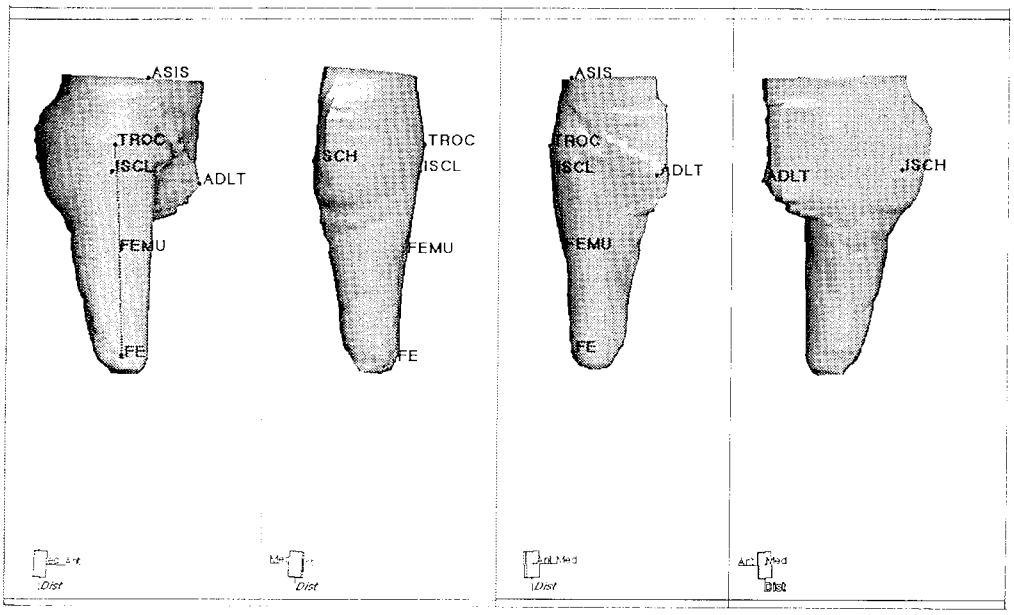

Figure 12.
Lateral, posterior, anterior, and medial views of the residual limb measurement data from the optical scan of the test subject with right AK amputation in Figure 10 are shown input into the VA-Seattle ShapeMaker CAD System for prosthetic socket design.

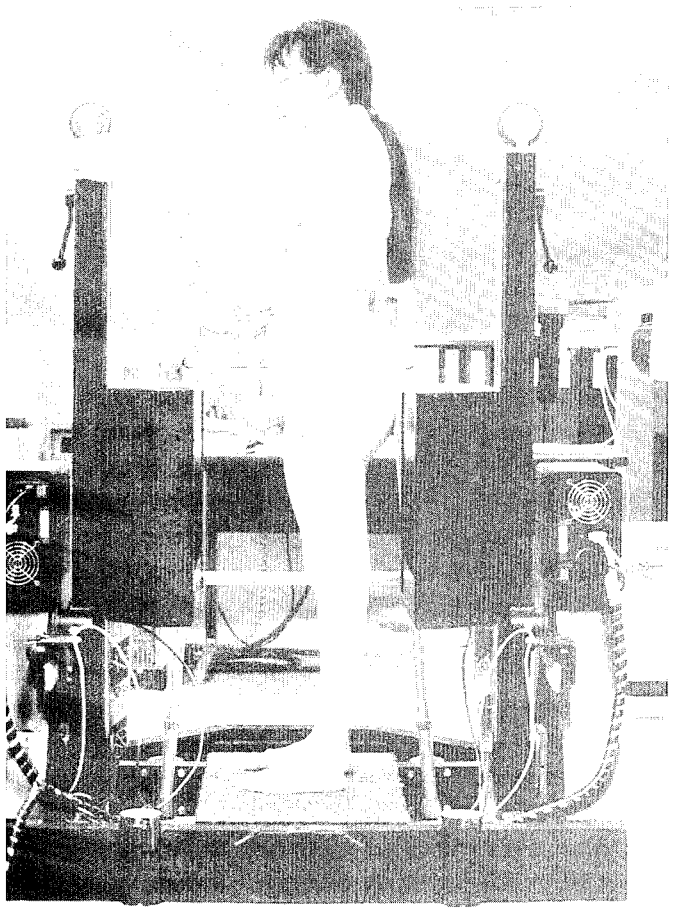

Figure 13.
Clinical application of the VA-Cyberware Optical Laser Digitizer in measurement of the spatial geometry and surface topography of the lower limb of a neuromuscularly impaired orthotics patient.

measurements due to light specularly reflected from the markers. The locations of the markers in the data thus become more prominent. Identification of which residual limb anatomical features correspond to which of the detected markers is not readily apparent, however, in the camera output intensity data obtained from the digitizer as a function of pixel number and cross-sectional scan number. A further transformation of the data through optical triangulation, to the equivalent function relating camera output intensity to the scan field (x, y, z)—spatial positions "viewed" by each of the camera pixels at the respective cross-sectional scan heights—is necessary to facilitate identification of which residual limb anatomical feature(s) correspond to the respective detected optical markers. Detection of residual limb or limb segment landmarks is further enhanced by quantization of the transformed output intensity data into discrete levels, with subsequent mapping of the resulting levels into distinct, contrasting, coded colors. As shown in **Figure 17,** such contrast enhancement of the camera output intensity measurements causes the optical markers to appear as small, circular regions superimposed on the lighter, shaded image of the residual limb. In addition, transformation and enhancement of the digitizer cameras' output intensity measurements facilitates application of a pattern recognition scheme for automated landmark identification and registration, such as the "blackboard" scheme (5) currently under development by NY VAMC and Wright Patterson Air Force Base CARD Laboratory researchers.

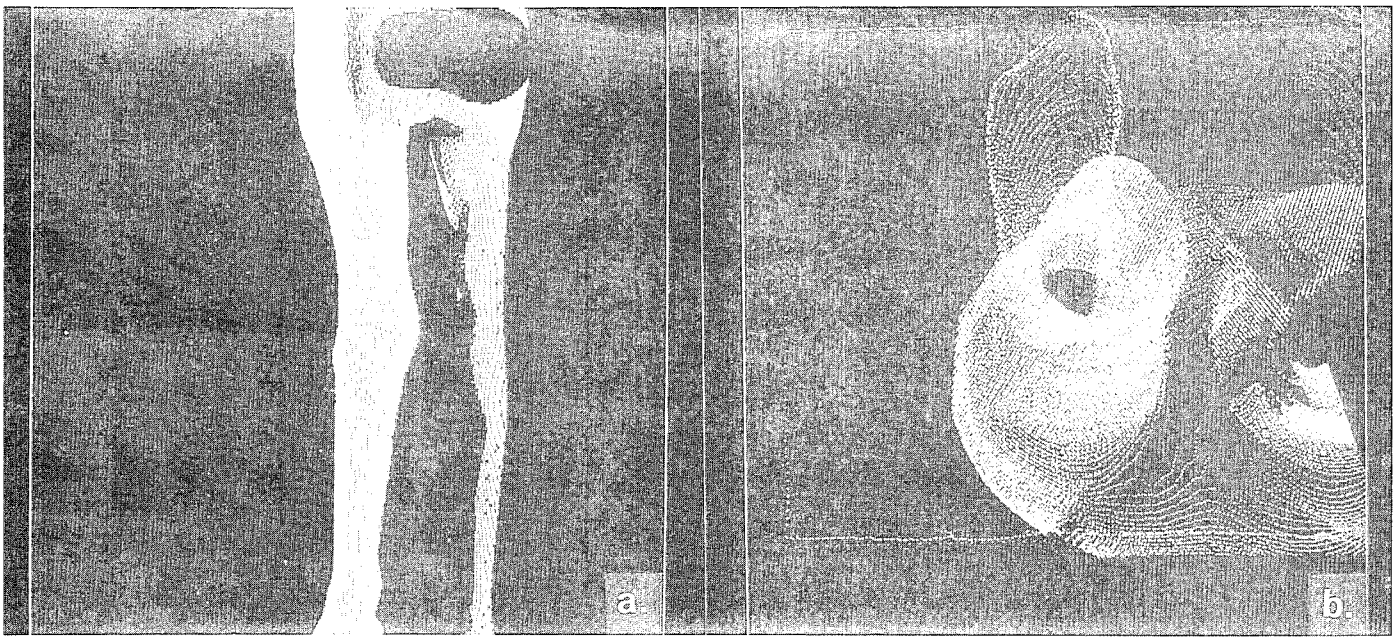

Figure 14.
The optical digitizer cameras' pixel measurement data from the scan of the left lower limb of the orthotics patient shown in Figure 13. The slave scan head's pixel measurement data of the posterior surface of the subject's pelvis and left leg are shown in (a). The distal view (from the floor up) of the master and slave scan heads' composite pixel measurement data is shown in (b). The pixel measurement data have been mapped into their corresponding scan field (x,y,z)-spatial coordinates, but are otherwise unprocessed. The digitizer's ability to completely capture the surface contours of the subject's limb, from the crest of her ilium to the plantar aspect of her foot, is evident.

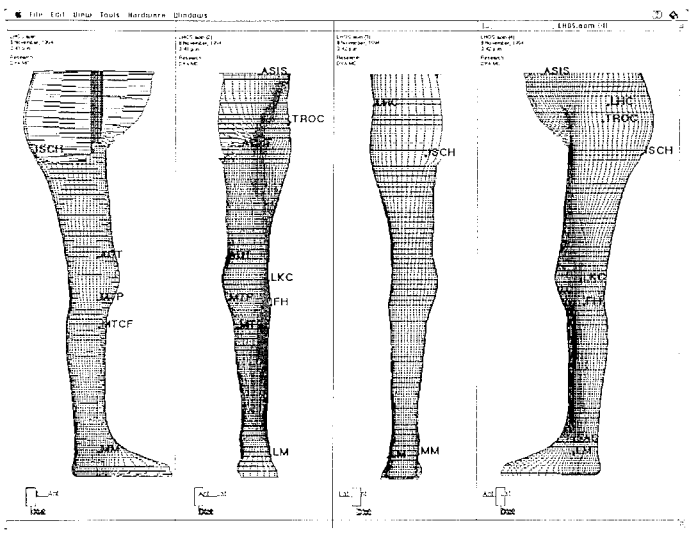

Figure 15.
Lateral, posterior, anterior, and medial views of the measurement data from the optical scan of the left lower limb of the orthotics patient in Figure 13 are shown input into the VA-Seattle Shape-Maker CAD System for knee-ankle-foot orthosis (KAFO) design.

Figure 16.
Pedorthic application of the VA-Cyberware Optical Laser Digitizer for measurement of the spatial geometry and surface topography of patients' feet and ankles. The horizontal plane of light from the digitizer scan heads' lasers can be seen incident on a transverse cross section of the patient's foot during the scanning process.

As part of the investigations with the VA-Cyberware Optical Laser Digitizer prototype, comparative clinical studies were performed in which test subjects with BK and AK amputation were optically scanned, and the relative positions of designated residual limb reference frame landmarks recorded. The subjects' residual limbs were also cast with plaster bandage, the resulting casts were then digitized

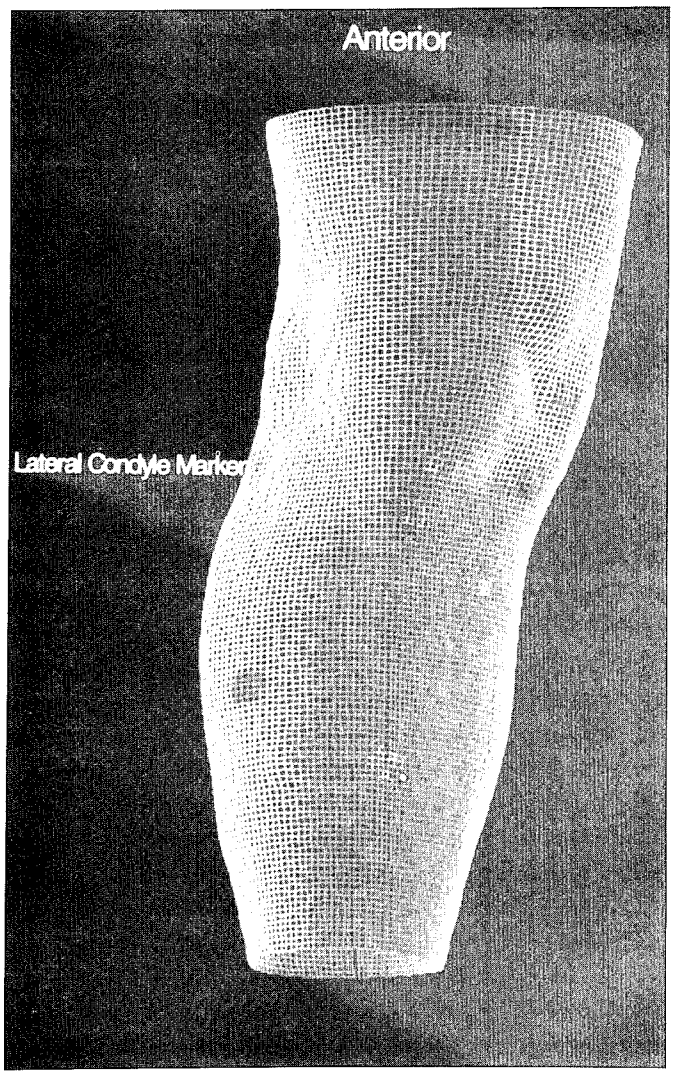

Figure 17.
Detection and identification of residual limb landmarks from the optical digitizer's cameras' output intensity measurements. Color encoded markers were placed on a right BK amputee test subjects' residual limb femoral adductor tubercle, medial femoral epicondyle, lateral femoral epicondyle, mid-patellar tendon, medial tibial condylar flare, fibular head, fibular end, and mid-tibial shaft crest prior to optical digitization. The digitizer scan heads' cameras' output intensity measurements from the resulting scan of the subject's residual limb are shown mapped via optical triangulation into their corresponding (x,y,z)-spatial coordinates, bandpass filtered at the optical marker intensity variation frequencies, and contrast enhanced to improve the detectability and identifiability of the landmarks.

using the NY VAMC Prosthetics CAD/CAM electromechanical digitizer, preserving the spatial locations of the given reference frame landmarks. The sets of optically digitized measurements and electromechanically digitized plaster wrap cast measurements for each subject were then mutually aligned and analyzed.

Considerable care was taken in the clinical studies to control experimental variables. A single engineer and single prosthetist performed all of the optical scans. They meticulously identified and marked the reference landmarks on the residual limbs of each of the subjects, and carefully, and as consistently as possible, aligned the residual limb of each subject for scanning and casting. Similarly—to maintain consistency in experimental technique, and minimize measurement variability and error—all test subjects were cast by the same prosthetist. During casting, the project prosthetist expended considerable effort to avoid displacing or distorting the subjects' residual limb tissues (the same type of plaster bandage was used for each subject, applied proximally to distally in a medial-to-lateral direction, without modification or molding of the residual limb tissues, and with application of only enough tension to prevent wrinkling of the plaster bandage). In addition, to minimize the potential for edematous swelling, the subjects were asked to remain in their prostheses until the time of scanning and casting, and to re-don their prostheses and walk about in the interval between scanning and casting. Half of the subjects were optically scanned first, and half were cast with plaster bandage first. As an additional control, multiple scans and multiple casts of four of the test subjects were taken and analyzed.

For the multiply scanned BK and AK subjects, maximum volumetric deviations of 1.2 percent and 3.0 percent were observed, respectively. However, most of the optical scans for these subjects evidenced volumetric variations of 1.0 percent or less. Volumetric variations of 7.6 percent and 12.3 percent were found in the undistorted plaster wrap casts for the multiply cast BK and AK test subjects, respectively. No correlation between scanning or casting order and the magnitude of the variations observed in the resulting scans or casts was found upon analysis of the data. Edematous swelling of the subjects' residual limb tissues was therefore discounted as a causative factor for the residual limb scan and cast measurement variations that were observed. A strong correlation was found, however, between the contractile state of the test subjects' residual limb musculature and the residual limb segmental volumes optically measured. Specifically, it was discovered that some subjects, when told to "hold perfectly still" during the scanning operation, inadvertently isometrically contracted their muscles, thereby changing the shape and increasing the volume of their residual limbs. Precautions were thence taken to instruct the test subjects not to tighten

their muscles during the scanning procedure. The 20-min time period involved in the residual limb casting procedure, however, is felt to preclude muscular contraction as a causative factor in the electromechanically digitized plaster wrap cast variations that were observed. The magnitudes of the intra- and intersubject cast measurement variations that occurred indicate that substantial differences existed in the subjects' cast/residual limb tissue interface stresses. Such interface stress variations are believed to almost certainly be attributable to deviations in plaster bandage application tensions, and differences in the subjects' residual limb tissue viscoelastic responses to radial and tangential loading. To the extent possible, these factors were controlled by the investigators. They still inherently led to greater variations in the electromechanically digitized plaster wrap cast measurements than the factors correspondingly adversely affecting the optical scan measurements. This demonstrates the enhanced consistency and repeatability afforded by optical digitization in characterizing residual limb and limb segment spatial geometry and surface topography. It also demonstrates the increases in cast/limb tissue interface stresses—potentially adversely impacting localized tissue circulation and metabolism, especially in chronic diabetic and atherosclerotic patients (6)—that can arise as a result of the residual limb or limb segment casting process. These stresses are inherently carried through into the prosthetic socket/ orthotic cuff designed and manufactured from the casts.

Typical examples of the *results* obtained in the *clinical tests* are shown in **Figures 1, 2, 9,** and **12.** The additional geometric and topographic information contained in the optically digitized residual limb measurements is clearly evident in **Figures 9** and **12,** compared with the electromechanically digitized plaster wrap cast measurements for the same subjects shown in **Figures 1** and **2,** respectively. Quantitative analysis of the data obtained from the two measurement techniques shows that, although the optically digitized and electromechanically digitized plaster wrap cast measurements were similar for each subject, they were not geometrically identical. Computation of cross-sectional circumferences, areas, and segmental volumes of the test subjects' residual limb measurements reveals the optically digitized measurements, on the average, to be larger than the corresponding electromechanically digitized plaster wrap cast measurements. In addition, the optically digitized measurements were found to be slightly axially longer, on the average, than the corresponding electromechanically digitized plaster wrap cast measurements. However, as seen in **Figure 18,** this was not true for all of the subjects tested. For some subjects, the cross-sectional circumferences, areas, and segmental volumes of their electromechanically digitized plaster wrap cast measurements were larger than their corresponding optically digitized residual limb measurements.

The magnitudes of the intersubject variations in the residual limb measurement differences shown in **Figure 18** are too large to be attributable to intrasubject optical scan and electromechanically digitized plaster wrap cast measurement deviations, as established from the multiply scanned and cast test subjects. Other factors must have produced the large variations observed. The data in **Figure 18** are presented in order of increasing residual limb length. Calculation of the sample correlation coefficient for the data indicates there is no appreciable correlation between residual limb length and optical scan—electromechanically digitized plaster wrap cast measurement deviation. Further analysis of the measurement variance reveals mild correlation between residual limb measurement deviation and the qualitatively assessed residual limb tissue stiffness of the subjects. The study sample sizes in the "very soft" and "firm" tissue stiffness categories, however, were too small to accurately predict trends. Additional inspection of the measurements in **Figure 18** reveals residual limb tissue parametric variations common to all of the test subjects. Specifically for the subjects with BK amputation who were tested, the differences in residual limb cross-sectional circumferences, areas, and segmental volumes measured at the femoral epicondyle (FC), mid-patellar tendon (MPT), and medial tibial condylar flare (MTCF) levels were found to all either shift up or down, indicating a proximal and/or distal flow of the subjects' soft tissues during plaster wrap casting of their residual limbs (**Figure 18a**). The more limited data in **Figure 18b** indicate similar factors and conditions occurred for the AK test subjects as well.

Despite the great care taken to avoid residual limb tissue distortion and displacement during the casting process, cross-sectional rounding and distortion were observed in the electromechanically digitized plaster wrap cast measurements of all of the subjects. In comparison, the subjects' optically digitized residual limb measurements were found to be more "normal" and anatomical in shape. This was especially true for the tested subjects with AK amputation. The reduced internal mechanical structural (skeletal) support, and the greater volume of soft tissues, increased the susceptibility of the residual limb tissues of the AK amputees to displacement and distortion, when subjected to external stresses (such as the surface tensions and radial compressions inherent in circumferentially

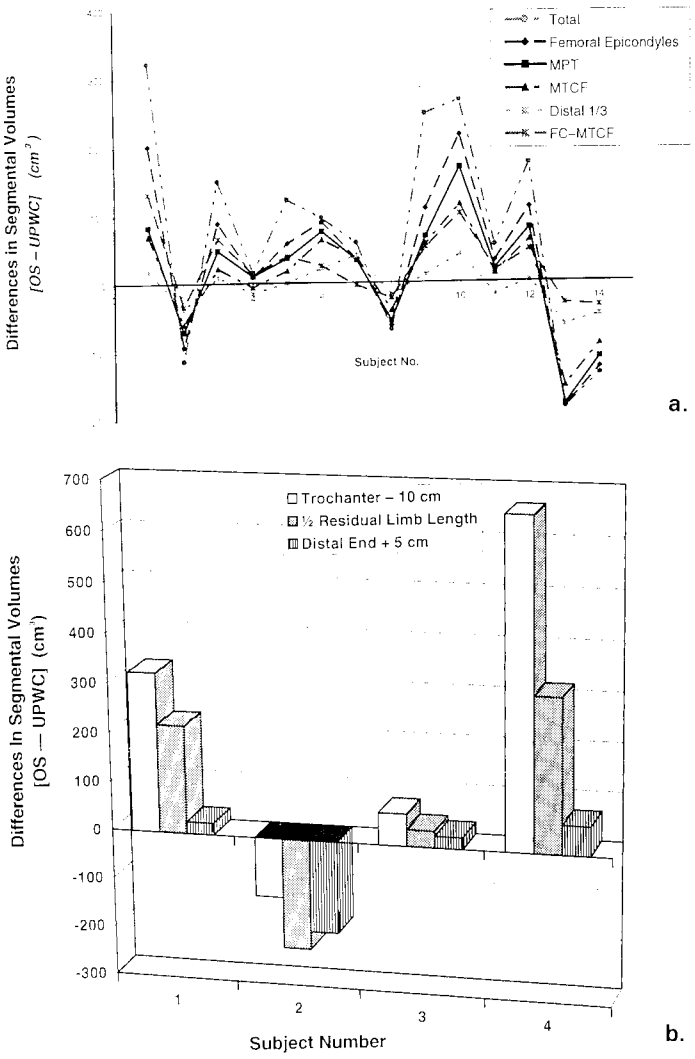

Figure 18.
Differences in residual limb segmental volumes observed between optically digitized measurements and corresponding standard prosthetics CAD electromechanically digitized unmodified plaster wrap cast measurements for (a) 14 test subjects with BK amputation and (b) four test subjects with AK amputation. The differences (optical scan values minus electromechanically digitized unmodified plaster wrap cast values) are shown in order of subject increasing residual limb length.

wrapped plaster bandage). This resulted in the significant differences in geometric shape observed between the subjects' optically digitized and electromechanically digitized plaster wrap cast measurements. This is evident in the comparative anterodistal views of an AK test subject's optically digitized and corresponding electromechanically digitized plaster wrap cast measurements shown in **Figure 19.** Marked cross-sectional rounding, as well as considerable proximal displacement, of the residual limb tissues of the subject is evident in the electromechanically digitized plaster wrap cast measurements in **Figure 19.**

The regional differences that occurred between the test subjects' optically digitized and corresponding electromechanically digitized plaster wrap cast measurements were further illustrated through calculation of radial comparative AFMap plots for the test subjects. In the VA-Seattle Shapemaker AFMap plots, optically digitized residual limb measurements were mutually aligned with, and superimposed on, the corresponding electromechanically digitized plaster wrap cast measurements. The radial difference between the optically digitized and the plaster wrap cast electromechanically digitized measurements over each nodal region of the subject's residual limb were then displayed as a color-encoded value (7). Significant differences between the optical scan and electromechanically digitized plaster wrap cast measurements over the BK test subjects' medial femoral condyles, patellar tendons, medial tibial condyles, fibular shafts, and the distal ends of the residual limbs of the subjects were observed. Differences over the subjects' popliteal gastrocnemius regions were usually less significant. Marked differences were observed for the subjects with AK amputation in the measurements obtained from the two techniques. Major differences occurred over the subjects' Scarpa's triangles, the proximal anterolateral and anterolateral-to-mid-lateral aspects of their residual limbs, and the distal ends of their residual limbs. Significant differences were also frequently found over the subjects' posteromedial gluteal and proximal perineal regions. All these regions are crucial in prosthetic socket design. They require accurate modification to within close tolerances of the patient's musculoskeletal dimensions to achieve successful socket fit, comfort, and function. This is a requirement that is difficult to attain through application of "generalized" prosthetics CAD modification templates, or through application of fixed conventional prosthetics socket modification paradigms, if the relative amounts, locations, and shapes of the residual limb or limb segment tissues vary appreciably and seemingly unpredictably from cast-to-cast and from patient-to-patient.

DISCUSSION

The broad applicability, high level of performance, and enhanced repeatability and consistency achievable with the VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer have been established in

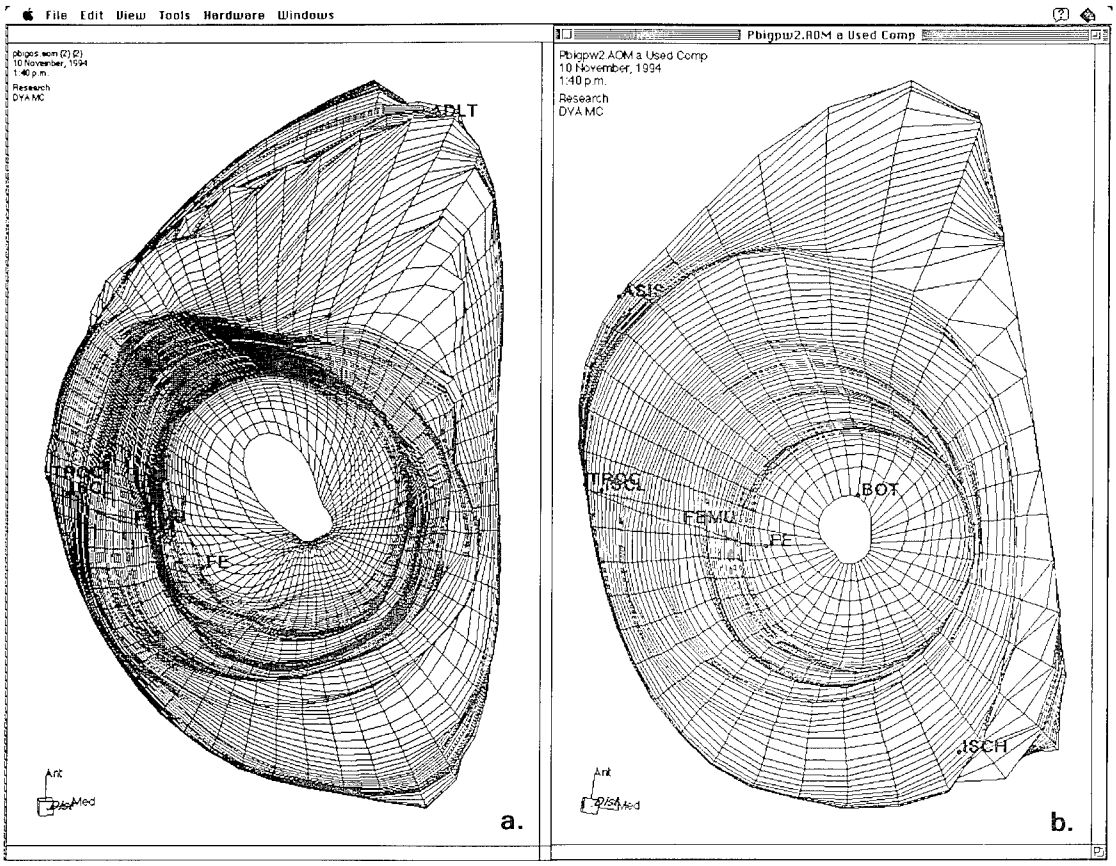

Figure 19.
Anterodistal views of the (a) optically digitized and (b) corresponding electromechanically digitized unmodified plaster wrap cast measurements, of the residual limb of a test subject with right AK amputation. The more "natural" shape of the optically digitized residual limb measurements is apparent, compared with the rounded and proximally displaced tissue geometry inherent in the electromechanically digitized unmodified plaster wrap cast measurements.

the tests we have performed. The laboratory and clinical tests have also identified several areas where the current digitizer prototype requires further refinement. In particular, the 28-cm-deep × 30-cm-wide × 95-cm-high scannable spatial envelope of the current prototype has been shown to be insufficient. Patients with amputation and orthotics patients whose anteroposterior and/or mediolateral dimensions exceed these values, or who have long residual limbs or limb segments with hip and/or knee joint flexion contractures exceeding 20°, causing their (residual) limbs to protrude outside of the scannable envelope, cannot be completely "seen" by the digitizers scan heads' cameras.

Three other subtler factors affecting the digitizer's performance identified in our laboratory tests are 1) nonuniformities in the intensities and dispersions of the prototype digitizer scan heads' lasers; 2) lack of matching in the optical characteristics of the prototype digitizer scan heads' optical components; and 3) nonuniformities in the output responses of the prototype digitizer scan heads' cameras. As seen in **Figure 6,** these factors adversely impact the digitizer scan heads' cameras' fields of view, depths of field, and output responses. The severity of these effects was found to differ significantly between the digitizer prototype's master and the slave scan heads, causing nonuniformity of the data obtained from the heads. This further complicated estimation of residual limb and limb segment contours using the composite data from the two scan heads.

In the outer regions of the scan heads' fields of view, as shown in **Figure 6,** the CCD cameras' optical lines of sight bend and separate from each other more than at the centers of the cameras' fields of view. The effects of these nonuniformities and nonlinearities on the outputs of the scan heads' cameras' pixel and intensity output responses, from which the (x,y)-coordinates of the digitized objects' surface contours are estimated, can, and have, to the extent

possible, been compensated for through incorporation of empirically established optical compensation algorithms in the digitizer image generation and processing software. However, it is impossible to correct for the loss of resolution precipitated by these effects. The increase in spacing between the scan heads' cameras' adjacent optical lines of sight at the periphery of the fields of view, results in an increase in the portions of the digitizer's scannable envelope that are mapped into individual pixels on the scan heads' CCD cameras. As a consequence, the maximum resolution achievable over the outer portion of the digitizer's scannable envelope is only ± 3.0 mm anteroposteriorly and ± 1.5 mm mediolaterally. Whereas, at the center of the scan heads' cameras' fields of view, the optical lines of sight are more uniformly and closely packed, so that resolutions of < ± 0.5 mm are achieved. In scanning the residual limbs of subjects with AK and BK amputation, and the lower limb segments of orthotics patients, accurate characterization of the contours of the limb, and precise determination of the locations of key anatomical structures on the lateral aspects of the limb (e.g., the trochanter, distal end of the femur, fibular head, fibular end, malleoli, etc.) are essential. For patients of medium-to-large stature, these structures inevitably lie in the peripheral regions of the digitizer's fields of view, and are thus less accurately detected, or may be lost altogether. In addition, for accurate detection of lateral contours, brighter lasers with more uniform fields of illumination, matched between each of the scan heads, are needed. Brighter lasers with more uniform illumination are also essential for improvement of landmark detectability. When the color encoded markers used for anatomical landmark detection lie in the center of the digitizer scan heads' cameras' fields of view, they are readily detectable via bandpass filtering and contrast enhancement of the camera output intensity measurements (**Figure 17**). However, because of the nonuniform, dispersive illumination produced by the prototype digitizer's lasers, when the markers fall near the periphery of the scannable envelope, the intensity of the light (the signal) reflected from the markers is weak, so the markers begin to become indistinguishable from the ambient and background light reflected from the surface of the patient's residual limb or limb segment (background noise). This is apparent in the diminished detectability of the BK test subject's lateral femoral epicondyle and fibular head markers in **Figure 17.**

Clinical testing of the digitizer with pedorthics patients revealed two additional problems. The digitizer prototype was designed so the uprights could be unlocked and pivoted 90° into a horizontal position. A chair could then be placed within the frame of the digitizer, and a pedorthics/orthotics patient seated with his or her foot placed in partial weightbearing on the glass plate of a support fixture inserted between the horizontally rotated uprights. The scan heads could then be driven horizontally along the uprights' translation rails, scanning transverse cross sections over the medial, lateral, dorsal, and plantar surfaces of the patient's foot and ankle (**Figure 20**). *Clinical pedorthic testing* of the digitizer showed the digitizer functioned properly mechanically. However, differences in the indices of refraction between pedal soft tissues, glass, and air, together with the acute angle of incidence of the scan heads' laser light, were found to produce up to five planes of laser light incident on patients' feet, resulting from

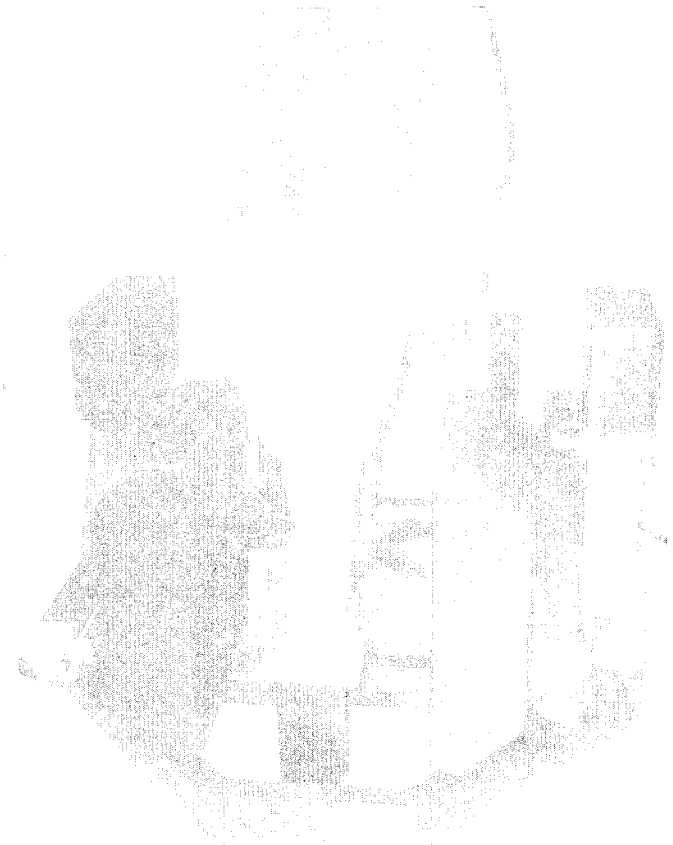

Figure 20.
Pedorthic scan mode of the VA-Cyberware Optical Laser Digitizer prototype as originally designed. The patient is seated on a chair in the base of the digitizer; the uprights, scan heads, and translation assemblies are rotated 90°; and the patient's foot/ankle is positioned and aligned in partial weightbearing on a pedal support fixture located between the horizontally rotated uprights and scan heads.

multiple reflections in the support fixture glass plate (**Figure 21**). The spurious signals from these multiple reflections irrevocably corrupts the digitizer camera output data, making it impossible to estimate cross-sectional contours where the multiply reflected light is of appreciable intensity. In addition, it was discovered that upon derotation of the digitizer uprights back to their vertical positions, the scan heads did not precisely return to their original positions. This necessitated laborious recalibration of the digitizer, and computation of new correction coefficients to compensate for the nonlinearities in the scan heads' optics. Thereafter, the horizontal scanning mode for pedorthic applications was abandoned.

A new, enhanced digitizer prototype is currently being constructed with 1) brighter and more uniformly illuminating lasers; 2) matched linear optics; 3) CCD cameras with approximately four times the resolution of those in the current prototype; and 4) an expanded scannable envelope at least 35-cm-deep × 40-cm-wide × 130-cm-high, with scan head "standoff" distances of at least 10 cm. These refinements should remedy the problems encountered in testing the first optical digitizer prototype, with the exception of those associated with horizontal pedorthic scanning, which, for now, has been replaced with the vertical scanning procedure shown in **Figure 16.**

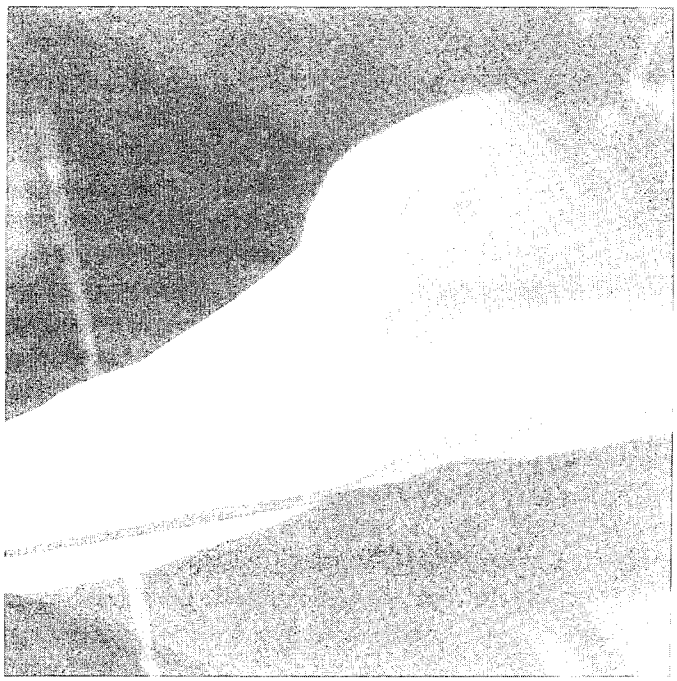

Figure 21.
Laboratory simulation demonstrating the problems inherent in the prototype optical digitizer's original pedorthic scan mode design. Five planes of laser light can be seen incident at the lateroplantar-dorsal edge of the cast of a pedorthics patient's foot/ankle. The multiple, incident planes of laser light result from reflections in the glass plate of the digitizer's pedal support fixture, because of differences in the indices of refraction between the patient's pedal tissues (simulated by the plaster cast), the pedal support fixture's glass plate, and air (the coupling medium between the scan heads' lasers and the glass plate of the pedal support fixture).

CONCLUSION

The VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer has been shown to be a powerful tool, capable of effectively and rapidly generating accurate, repeatable, and consistent quantitative measurements characterizing the spatial geometry and surface topography of the residual limbs of persons with amputation and the limb segments of orthotics and pedorthics patients. When the deficits identified in the original digitizer prototype design are corrected, and the new, enhanced prototype under construction is tested, the optical digitizer will be ready for widespread field-testing and general clinical use. The digitizer can then begin to be utilized by prosthetists, orthotists, physicians, and therapists in clinical practice, and in expanded studies and applications 1) for quantitative database compilation of residual limb and limb segment measurements for development of improved prosthesis/orthosis/pedorthosis CAD designs; 2) for compilation of quantitative patient records and histories for assessment of residual limb "state" and rate of "maturity" following amputation; 3) for tracking and assessment of the efficacy of various rehabilitative and/or pharmacological treatment regimens in regulating and controlling tissue edema/volume/mass; 4) for tracking the relative spatial locations and trajectories of adjoining limb segments as a function of their biomechanical functional state; and 5) as an instructional aid to facilitate visualization and understanding of prosthesis-orthosis-pedorthosis design, fit, and function. In all of these areas, the VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer offers potential for improving and enhancing the quality of prosthetic, orthotic, and pedorthic rehabilitative care for U.S. veteran (and nonveteran) patients.

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CLINICAL REPORT

Clinical Evaluation of the Franklin Applied Physics Cosmetic Cover for Lower Limb Prostheses: A Preliminary Report

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Abstract—The Franklin Applied Physics (FAP) Cosmetic Cover is the result of research and development directed by Dr. Robert Erb at the Franklin Research Center, Norristown, PA. The FAP Cover is a silicone rubber cosmesis designed to improve the appearance of lower limb prostheses and provide wider social integration for the wearer.

The Technology Transfer Section, Rehabilitation Research and Development Service, Department of Veterans Affairs, coordinated a pilot study of four pre-commercial covers at selected sites. Participating prosthetists and subjects evaluated fit, relevant physical criteria, and overall potential value of the cover.

The following statements summarize responses of the participants: 1) well accepted with regard to overall fit, appearance, and ease of donning/doffing; 2) lightweight, highly elastic, and easy to maintain; and 3) split toe and closed toe versions are needed for above-knee and below-knee models.

Data gleaned from the pilot study were used to define dimensions for standardized off-the-shelf sizing and to make recommended modifications, resulting in pre-market models that are ready for a national field evaluation.

Key words: *above-knee amputations, above-knee prostheses, below-knee amputations, below-knee prostheses, technology transfer.*

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INTRODUCTION

In 1985, responding to the need for a life-like, durable, functional, and affordable cover for lower limb prostheses, the Department of Veterans Affairs (then called the Veterans Administration), Rehabilitation Research and Development Service (VA Rehab R&D) sponsored the Franklin Research Center (FRC), Norristown, PA, in developing a silicone rubber cosmesis. During the next 5 years, Dr. Robert Erb directed this pioneering research at FRC. Over this period, several design prototypes were developed and tested, leading to the current process and materials used. Laboratory tests conducted at FRC on the prototypic models proved successful and FRC eventually submitted a Request for Evaluation (RFE) for review and consideration as a technology transfer project. After review, the device was deemed ready for clinical evaluation as a desirable prosthetic component.

Franklin Applied Physics, Inc. (FAP) in Oaks, PA,[1] under the direction of Christine Felser (formerly with the research team at FRC), with Dr. Robert Erb and Harold Heller serving as consultants, produced four covers for the pilot evaluation. The FAP Cosmetic Covers (three medium-sized right below-knee covers and a large left above-knee cover) were fabricated with a split between the great toe and second toe to fit the M + IND Seattle Lite Foot (SLF).

[1] The Franklin Research Center was closed on January 31, 1993.

Since the FAP Cosmetic Cover had never been clinically evaluated, the Technology Transfer Section (TTS), VA Rehab R&D Service, Baltimore, MD with collaboration from Frederick Downs, Jr., Director, and John Clements, VA Prosthetic and Sensory Aids Service (PSAS), accomplished a pilot evaluation prior to implementing the national field study. It was felt that results gleaned from this pilot would greatly assist in ensuring an efficient and effective multicenter evaluation.

PRODUCT DESCRIPTION

FRC researchers developed procedures for molding, casting, intrinsically coloring, and applying silicone prosthetic covers. The manufacturing process involves fabricating the covers using a multistep molding procedure of a two-part room temperature vulcanizing (RTV) silicone rubber to provide highly detailed, dimensionally stable molds. The seamless molds replicate skin texture to give a realistic appearance to the outer layers of the cosmeses. These molds are now being targeted for standard off-the-shelf sizes to reduce costs and to increase availability.

The cover is a thin-walled silicone rubber cosmesis (**Figure 1**) designed for veterans (and others) with lower limb prostheses. The developers state that the advantageous properties of the FAP Cover are its life-cast surface features, realistic appearance, and elasticity. The water-repellent cover is designed to improve the appearance of a prosthesis; thus, providing wider social integration for the wearer (e.g., where informal clothing, such as shorts or skirts, is being worn and in situations where the wearer is barefoot).

The outer layers of the silicone rubber used for fabrication are pigmented with low levels of dry pigment to achieve the realistic semitransparency of human skin. The permanent intrinsic coloration process allows for standardization of the representative colors for the range of average human pigmentations. The intrinsic coloration process also permits the introduction of realistic heterogeneous mottling and spotting (**Figure 2**).

The intrinsic painting is done in multiple layers, which may include a base color, blush, and vein color. If necessary, FAP can select the base color by matching the veteran's skin shade to a color chip from the Munsell Skin, Hair, and Eye coloration chart. The Munsell color chart provides a systematic representation of the range of human skin colors in a format that allows the color chips to be placed next to the client's skin. An accurate color match of the hue, chroma, and value within the epidermis can be matched on the artist's pallet. By using quantitative measurements of silicone and pigments, the skin tones of all races of people can be duplicated. The pigments are then sealed within the layers of silicone, enabling the cover to retain this coloration during everyday wear and cleansing.

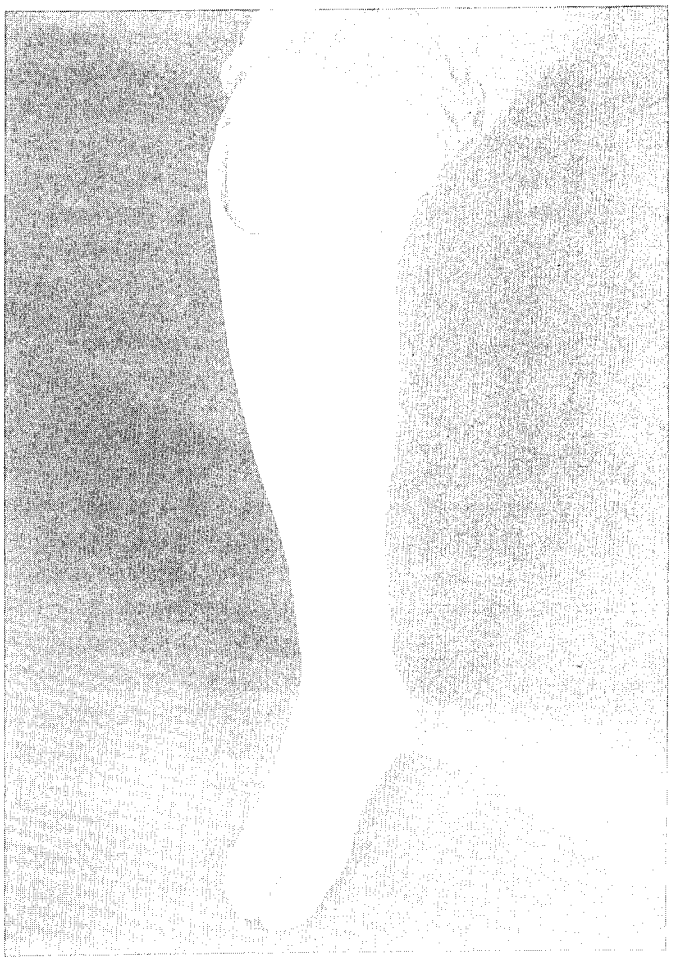

Figure 1.
Franklin Applied Physics (FAP) Cosmetic Cover.

Since the cosmesis is fabricated from high tear-strength silicone rubber, it has excellent abrasion resistance and durability. The silicone is comparable in tensile strength and tear strength to latex rubber, but is inherently superior to polyurethane. Silicone rubber is stable from chemical and photo-oxidative attack and also provides flexibility and stretching where needed (e.g., at the ankle and knee joint areas). The cover is essentially maintenance free. It may be cleaned, when necessary, with soap and water. Chemicals (e.g., rubbing alcohol), may be used to lift off ink marks and other small soil marks, if required.

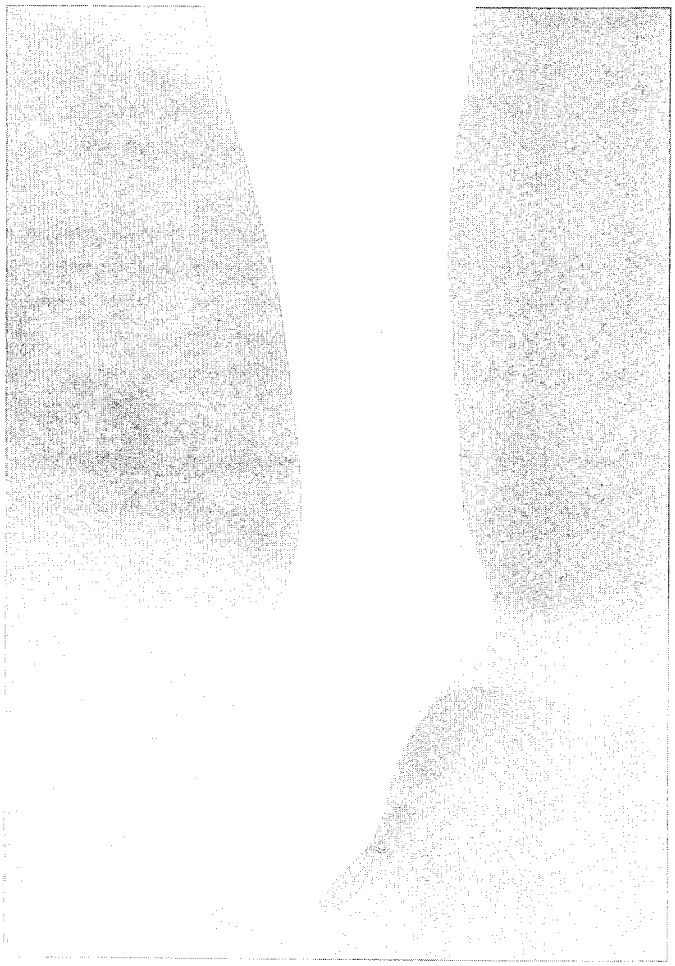

Figure 2.
Close-up of FAP cosmetic cover showing realistic heterogeneous mottling and spotting.

The wearer may use a disinfectant to prevent microbial growth.

Additional features of the FAP Cosmetic Cover are:

- The silicone used is a tear-resistant elastomer providing up to 800 percent elongation before breaking
- It is available for both below-knee (B/K) and above-knee (A/K) prostheses in medium and large sizes
- The surface texture is replicated directly from human skin
- The color is permanent; it will not fade or migrate.

SUBJECT CRITERIA

Male subjects with unilateral or bilateral B/K and A/K amputation who had worn a prosthesis for at least 1 year, and had worn their current prosthesis daily for the last 3 months, were selected to participate in the evaluation trials.

For the purposes of this study, the principal investigator (PI) or designee screened potential subjects according to the following criteria:

1. Ability to wear the prosthesis all day and leaves his residence a minimum of three times per week.
2. Ability to negotiate stairs and other common features of the residence.
3. Ability to independently perform all relevant activities of daily living (ADL).

The subjects were required to be active, alert, cooperative, and have a desire to participate in the evaluation and complete all data instruments.

The participating prosthetists and/or subjects were provided with detailed instructions for fitting by Franklin Applied Physics. The prosthetist and/or subject donned the cosmetic cover and the fit was observed. If the prosthetist and subject concluded that the fit was not satisfactory, the probable reason for failure was assessed and the locations and amounts of required modifications recorded. If a successful fit was obtained, the prosthetist and wearer assessed ease of donning/doffing. The cosmetic covers were reevaluated after a 3-month trial period. The subjects were allowed to keep the covers if they so desired.

RESULTS

The results were formulated from responses contained in the data instruments. Due to the limited clinical exposure, results are qualitative rather than quantitative. The following summarizes the results for the four participating facilities.

Cosmetic Cover for Below-Knee Prostheses

Clinical Evaluation

One subject was fit with a medium right B/K cosmetic cover at each of the selected PSAS Prosthetic Treatment Centers. Each subject had worn a prosthesis for 17 or more years and the current prosthesis for 6 or more years; all wore their prostheses 13 or more hours per day, 7 days per week. Information describing the subjects' current prostheses is included in **Table 1.**

All subjects rated the fitting instructions as adequate. For each wearer, the total time required to complete the fitting was from 30 to 60 minutes. Donning/doffing was rated as easy; on the first attempt, one user was able to

Table 1.
Current Prosthesis of Subjects.

	Subj. A	Subj. B	Subj. C
Type of Prosthesis	Exoskeletal	Exoskeletal	Endoskeletal
Type of Foot	SLF	SLF	SLF
Foot Size	26 cm	26 cm	28 cm

Table 2.
Subject Rating of FAP Cosmetic Cover Criteria.

Feature	Excellent	Good	Fair	Poor
Fit	A	B	C	
Stretchability	A, B	C		
Weight	A, B	C		
Overall Shape		A, B, C		
Feel	A	B, C		
Surface Texture	A	B	C	
Skin Coloration	A	B, C		
Wall Thickness	A, B	C		
Ease of Cleaning	A, B	C		
Ease of Keeping Clean	A, B	C		
Overall Appearance	A	C	B	
Overall Satisfaction	A, B	C		

don/doff the cover independently. One wearer required no adhesive and two subjects used adhesive to secure the cover to their prostheses.

Overall fit was rated as fair to good. Some wrinkling was noted between the great and second toe; the cover was loose over the dorsum of the foot, and posteriorly in the mid-calf area.

The subjects were also asked to rate the following items related to cover performance. Results are indicated in **Table 2.**

Neither environmental factors (e.g., heat, cold), nor household chemicals affected the cover. Soiled areas were easily removed with soap and water and clothing dye stains were removed with cleaners (e.g., rubbing alcohol). There were no reports of tearing, pin holes, or other damage to the appliances. No skin irritation was noted.

Advantages over other covers that the subjects had used included greater tear strength and a more life-like appearance. One wearer noted that the cosmesis frequently clung to his pant leg while he donned his trousers or when he sat down.

Suggested modifications included developing both closed toe and split toe versions of the cover and establishing standardized sizes in accordance with the M + IND (M + IND, Seattle, WA) Seattle Lite Foot/polyurethane endoskeletal (under) cover dimensions. Other suggestions were to increase the overall length of the B/K model by several inches and to include a wider band at the top for the trim edge.

All wearers said they would readily use the FAP Cosmetic Cover if these modifications were made and the device was commercially available.

Prosthetic Laboratory Fitting Evaluation

The initial selection of sizes for the men's medium and large cosmetic covers were arrived at through a combination of methods. The FAP developers physically measured a large number of men's feet and legs in the Philadelphia, PA area and combined those data with information from a size chart for adult male prosthetic feet supplied by M + IND, Inc.

Judy Johnson, Prosthetist-Orthotist, Acting Chief, Orthotics Laboratory, VA Medical Center, Richmond, VA, and the TTS Project Manager, Baltimore, MD, conducted a fitting evaluation of the FAP medium right B/K cosmetic cover with a series of Seattle Lite Feet to determine which sizes could be fit with the cover.

The results of the evaluation were as follows:

1. The FAP Cover was too large for the 25-cm SLF.
2. The Cover fit the 26-cm SLF, but was too loose over the dorsum of the foot in the area from the proximal edge of the toes back to the ankle. This space could be filled with foam or another type of filler.
3. The Cover fit the 27-cm foot well, except for wrinkling at the proximal crease between the great toe and second toe.
4. The Cover fit the 28-cm foot well, but due to cosmesis stretching, the second toe became too big (about one-third wider than normal) and the proximal crease wrinkling described in #3 (above) persisted.
5. The Cover fit the 29-cm SLF also, but the area over the lateral maleolus became stretched; the proximal crease wrinkling and large second toe persisted.

It appeared from the laboratory evaluation that with minor modifications, the pilot medium right cover would fit the three largest sizes of the SLF (27–29 cm). We felt that fabrication of a second, smaller FAP Cosmetic Cover, to accommodate prosthetic wearers utilizing 25- and 26-cm SLF, would adequately encompass the range of Seattle Lite Feet (and other split-toed feet) utilized by male veterans.

Cosmetic Cover for Above-Knee Prostheses

A large, left A/K cover was delivered to the Prosthetic Research Study (PRS), Seattle, WA for evaluation. The cover proved to be too large to fit any of the available subjects. However, the PI attempted to determine the potential inhibitory effect of the cover on an A/K prosthesis wearer during ambulation. Placing Yates clamps vertically down the posterior side of the cosmesis to take up most of the excess material and simulate a tight fitting cover, the PI conducted an ambulation evaluation with one subject. The PI was pleased with the unrestricted motion allowed by the FAP Cover. While the cosmesis was being worn, it did not appear to significantly inhibit knee movement.

PRS felt the cover was not long enough and suggested increasing the overall length by 8 inches. The PI recommended using a protective sleeve over the prosthetic knee joint or placing compressed foam donuts above and below the knee joint to prevent the cover from being pinched by the joint during ambulation. PRS has supplied the developer with a series of recommended thigh circumferencial dimensions for both the medium and large size covers. A second A/K cover, which has been fabricated in accordance with the recommended dimensions, is being forwarded to PRS for evaluation.

DISCUSSION

The FAP Cosmetic Cover was well accepted by all the subjects participating in the pilot trials. For the B/K version, the overall fit was rated as good and all wearers felt that, with practice, they could easily don and doff the cover independently.

Trials for the B/K cover confirmed that the intrinsic coloration did not fade or migrate. For appearance, stretchability, and ease of maintenance, all subjects preferred the FAP Cover to previous covers they had worn.

The overall reaction to the FAP Cosmetic Cover was favorable, but the following changes and modifications were identified:

1. The large model was too large for all candidates in the PRS subject pool.
2. The medium cover, with minor modifications, will adequately serve as the large size cover.
3. A second size (medium) is being developed to fit wearers using 25–26 cm prosthetic feet.
4. The new molds for the medium and large cosmetic covers will be based on dimensions utilized for the 25-cm and 27-cm M + IND SLF/polyurethane endoskeletal (under) cover componentry.
5. Thigh dimensions recommended by PRS will be incorporated into both A/K models.
6. Both A/K and B/K versions will be lengthened and the trim band increased in width.
7. Closed toe and split toe models will be developed for all covers.

It was the general consensus of all users and staff that changes to these areas would lead to an improved cosmetic cover that is desirable by persons with lower limb prostheses.

Based on the results of this pilot study, it is recommended that the next phase proceed: a national evaluation of 46 additional FAP Cosmetic Covers to validate the optimal dimensions for standardized sizing, durability, and relevant physical characteristics. Only through this mechanism can we fully determine the device's practicality, clinical utility, and commercial readiness for veterans (and others) with lower limb prostheses.

The following areas will be scrutinized in this evaluation:

- Fitting
- Functionality (stretchability) when applying the device onto prosthetic limbs and during ambulation activities (for A/K Covers)
- Durability
- User acceptance of aesthetics (color tone, texture and shape)
- Comparative acceptance to currently used lower limb cosmetic devices
- Maintenance and repair
- Readiness for commercial availability.

ABSTRACTS OF RECENT LITERATURE

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Abstracts are drawn primarily from the orthotics and prosthetics literature. Selections of articles were made from these journals:

American Psychologist
Archives of Physical Medicine and Rehabilitation
Assistive Technology
Ergonomics
Hearing Rehabilitation Quarterly
Journal of Prosthetics and Orthotics
Journal of Visual Impairment and Blindness
Physical Therapy
Prosthetics and Orthotics International

PROSTHETICS, ORTHOTICS, AND RELATED TOPICS

Analyses of 94 Consecutive Spinal Cord Injury Patients using ASIA Definition and Modified Frankel Score Classification. Capaul M, Zollinger H, Satz N, et al. Reprinted from *Paraplegia* 32:583–587, 1994.

Serial neurological examinations were analysed on 94 consecutive spinal cord injury (SCI) patients admitted for rehabilitation to the Swiss Paraplegic Center at the Clinic Balgrist Zurich, Switzerland, between 1987 and 1992. Patients' data were examined adopting ASIA and modified Frankel definitions in order to compare the two classifications in terms of consistency and prognostic value. The modified Frankel definition was subdivided into five categories (A, B, C, D and E). On admission (discharge) 43 (37) patients were classified as Frankel A, 23 (11) patients in group B, 26 (42) patients in group C, 2 (2) patients as Frankel D and 0 (2) patients in group E. A qualitative analysis of the results on the base of a maximal score of 100 points (A = 0, B = 25, C = 50, D = 75 and E = 100 points) suggested a mean score improvement from 21.5 (± 22.5) to 29.0 (± 26.3) or 7.5 (± 7.1), regarding all 94 patients during follow up (admission/discharge). The median improvement was one modified Frankel grade (A/B to B/C). No detailed assessments were yielded concerning motor and sensory functions. Using ASIA definition, a continuous numerical score of motor and sensory function was observed. Recovery during follow up was determined by detailed motor and sensory function. For all 94 patients (quadriplegics and tetraplegics), the average motor recovery according to the ASIA definition was 9.4 (± 9.6). The mean ASIA motor score improved from 52.2 (± 17.3) on admission to 61.6 (± 17.9) on discharge. Light touch increased by 7.0 (± 10.3) from 72.7 (± 22.3) to 79.7 (± 22.7) and pinprick sensory function by 7.1 (± 13.6) from 69.2 (± 21.8) to 76.3 (± 22.2). Change in status was progressively unidirectional using both definitions. Comparing the ASIA guidelines with modified Frankel classification there was an unambiguous benefit using the new definition of ASIA, as a gradual change of motor and/or sensory function was more clearly documented for all cases by ASIA. Using modified Frankel score definition, the patient's classification may be unchanged, regardless of whether the status improved or remained stable. This was not the case using ASIA definition. It was not the intention in this paper to assess and compare the treatment of acutely spinal cord injured patients by (a) nonoperative and (b) operative treatment. [JEE]

An Analytical Model of Intervertebral Disc Mechanics. McNally DS, Arridge RGC. Reprinted from *J Biomech* 28:53–68, 1995.

The Intervertebral disc is a complex mechanical structure, and it is important to understand the loading of specific structures which might cause damage leading to failure or mechanical impairment. At present it is only possible to model such internal loadings owing to the extreme technical difficulties involved in experimental measurement. The simple analytical model described in this paper makes exact predictions of the loads carried by fibres and also their path within the annulus fibrosus, without pre-defining the fibre configuration.

The disc is modelled as an axially symmetric structure comprising a fluid filled centre, retained by a thin, doubly curved, fibre-reinforced membrane under tensile stress. The annulus is taken to consist of two lamellae reinforced by oppositely oriented collagen fibres that are free to follow paths defined by one of two geometrical rules. The predictive power and possible uses of the model are illustrated using boundary conditions experimentally determined from a typical young disc. The model was used to calculate the shape of the membrane surface, fibre path, volume of disc, area of annulus, length of fibre bundle and tension at a point along length of fibre. Equatorial fibre angle could be approximately predicted (to about 5°), since there was only a small range of valid solutions to the model. The predicted surface profiles, fibre loads and angles were found to be in reasonable agreement with published experimental studies. Two examples of how the static model might be used to calculate changes in disc morphology and loading are included to demonstrate how a wide range of experimental data and theoretical behavior might be incorporated. This analytical model is important since it enables exact solutions to be calculated for the forces acting at any point along a fibre, their paths and also the surface geometry, from a small number of physical measurements without the need to estimate the mechanical properties of individual areas of the disc. It facilitates the prediction of the behaviour of the disc under varying load by providing a framework that can be further developed using a wide range and combination of experimental conditions and theoretical relationships. [JEE]

Assistive Technology: Problems and Policy Alternatives. O'Day BL, Corcoran PF. Reprinted from *Arch Phys Med Rehabil* 75:1165–1169, 1994 (©1994 by the American Congress on Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation).

Assistive technology (AT), defined as any device or product system that increases the physical functioning or independence of persons with disabilities, is transforming the way disabled Americans live and work. Numerous studies show increases in independence, employment, and life satisfaction; yet, the acquisition of AT presents many problems for disabled persons, such as lack of funds to purchase AT, no centralized information and evaluation system, fraud and abuse by some providers, and denials of needed equipment by third-party payers. The proposed Health Security Act could provide a potential mechanism to address these problems, but whether AT should by covered under the Act has received little national attention. In this article we document the need and current funding alternatives for AT, and suggests possible short and long-range strategies to make AT more available for individuals with disabilities. [JEE]

Augmentation of Transfers for a Quadriplegic Patient Using an Implanted FNS System: Case Report. Marsolais EB, Scheiner A, Miller PC, et al. Reprinted from *Paraplegia* 32:573–579, 1994.

A 22 year old man with incomplete quadriplegia (C6-7) was unable to perform either a sliding or a pivot transfer. He was instrumented with an implanted functional neuromuscular stimulation (FNS) system, radio frequency-linked to a belt-worn controller. The system activated eight muscles selected from among quadriceps, hamstrings, posterior portion of the adductor magnus, gluteus maximus, and erector spinae, bilaterally. The two-stage implantation procedure included electrode implantation with percutaneous leads followed by stimulator implantation and removal of the percutaneous leads. All implants were well tolerated with no adverse effects. The subjects was able independently to put on the external controller portion of the system and to perform a standing pivot transfer with only standby assistance. An unexpected outcome of the FNS system use was increased voluntary upper body strength that resulted in improvement of the sliding transfer from 'inability' to 'independent'. [JEE]

Cementless Acetabular Sockets: Morphological, Microradiographical and Morphometrical Investigations on Ingrowth Behaviour. Lintner F, Bohm G, Huber M. Reprinted from *Med Orthop Tech* 114:233–237, 1994.

Aim of the study was to evaluate the ingrowth pattern of cementless implanted metal-backed self-tapping titanium sockets. Experimentally implanted and autopsy gained specimens were investigated by means of histology, microradiography and morphometry.

The histology shows a uniform pattern to typical osseous ingrowth onto the rough titanium surface.

Morphometrically an osseous coverage between 6.23% and 27.68% of the experimentally implanted sockets was evident, whereas after an implantation period of more than 3.1 years coverage rates of up to 55% can be seen.

The reasons for low osseous coverage rates are therefore on the one hand insufficient contact of the socket with the

bone stock and on the other hand an interposition of the preexistent cartilage of the acetabulum.

In case of primarily sufficient contact of the socket with the bone stock the morphological and morphometrical results point to a possibly stable long-term anchorage of the implants. [JEE]

Cervical Spine Injuries in the Elderly. Lieberman IH, Webb JK. Reprinted from *J Bone Joint Surg* 76-B:877–881, 1994.

We reviewed 41 patients over the age of 65 years (mean 76.5) who had suffered cervical spine injuries, 12 of them with neurological deficit. Eleven patients died during treatment, mostly from respiratory disease. Seven patients were treated by surgical stabilisation, five by halo traction, and the rest by rigid collars or halo-vests. The cervical injury was missed at the first examination in four patients.

We conclude that most injuries can be treated by a rigid collar, and the use of a halo-vest or surgical stabilisation are effective alternatives. Bed rest and traction are poorly tolerated by old people. There should be a high index of suspicion that any elderly patient who presents with a history of a fall or minor trauma may have a cervical spine injury. [JEE]

A Computer Assisted Follow up System for Spinal Cord Injury Patients. Levi R, Hultling C, Westgren N. Reprinted from *Paraplegia* 32:736–742, 1994.

The comprehensive care of patients with traumatic spinal cord injuries (SCI) necessitates, among other things, a structured, life-long follow up. The high consumption of medical care in chronic SCI patients, often a result of diseases affecting many different organ systems, soon causes the cumulated medical documentation to be extensive and therefore hard to survey. The possibilities for rational patient management, adequate quality assurance, and clinical research may improve considerably by computerisation of medical records. A computerised medical records system for SCI has recently been developed, using a semistructured medical record format for data input and a medical entity dictionary for facilitated data storage and retrieval. The principles for developing this computer-assisted follow up system are described. [JEE]

Determination of Gross Weight Limit for Foldaway Powered Wheelchairs through Isometric and Psychophysical Strength Simulations. Mital A. Reprinted from *Ergonomics* 37:1549–1561, 1994.

This study concerns the maximum weight of a powered wheelchair for transfer to and from the trunk of a car by individuals with limited exercise endurance. The loading and unloading of a folded wheelchair from the trunk of a medium size American car was simulated. Both static and dynamic simulations were carried out. The isometric (static) and psychophysical (dynamic) strengths of eight adult males while simulating the loading/unloading activities were measured. The results indicated that: (1) the maximum weight of a powered foldaway wheelchair that individuals can load in the car and unload from the car is much lower than the weight of most commercially available powered wheelchairs, and (2) static simulation of the folded wheelchair loading and unloading activity provides wheelchair weight ceiling that is easily exceeded during the dynamic simulation of the activity. The upper limit on the weight of a foldaway powered wheelchair is provided and implications of this limit on future foldaway wheelchair designs are briefly discussed. In addition, the user gender and age effects on the foldaway powered wheelchair weight ceiling are also discussed. [JEE]

The Effectiveness of Four Contemporary Cervical Orthoses in Restricting Cervical Motion. Lunsford TR, Davidson M, Lunsford BR. Reprinted from *J Prosthet Orthot* 6:93–99, 1994.

The cervical motion in three planes was evaluated in 10 subjects while they wore each of four contemporary cervical collars (Philadelphia, Miami J, Malibu and Newport Extended Wear) and no orthosis. The amount of force placed on the orthosis by the subject was controlled and monitored. The cervical motion was measured using three video cameras and a pointer attached to a mouth stick that was fitted over the lower teeth of each subject. The subjects sat in a custom-built chair and were secured by thoracic and pelvic straps to minimize extraneous motion.

The Malibu collar provided the greatest restriction in coronal flexion, sagittal flexion, sagittal extension and axial rotation (41, 40, 57 and 61 percent, respectively). Each of the four orthoses allowed significantly less motion than "no orthosis" at all for the motions evaluated. [JEE]

The Effects of Parallel Bars, Body Weight Support and Speed on the Modulation of the Locomotor Pattern of Spastic Paretic Gait: A Preliminary Communication. Visintin M, Bearbeau H. Reprinted from *Paraplegia* 32:540–553, 1994.

The effects of walking with and without parallel bars, providing 40% body weight support (BWS) and increasing speed on the gait pattern of spastic paretic subjects during treadmill locomotion were investigated. In asymmetrically involved subjects, walking without parallel bars led to a more symmetrical gait pattern with decreased compensation of the less involved side. This was accompanied by changes in electromyographic (EMG) and sagittal angular displacement profiles which favoured a more normal swing phase of the more involved limb. When symmetrically involved subjects walked without parallel bars, increases in EMG activity, with prolonged activation during the stance phase were noted, especially in the distal muscles. Providing 40% BWS facilitated gait when walking without parallel bars especially in the asymmetrically or severely involved subjects who showed marked difficulty at 0% BWS. Forty percent BWS led to a decrease in clonus associated with walking without parallel bars. Higher treadmill speeds increased clonus in some subjects while in others it only caused a small increase in EMG amplitude. Implications for gait training are discussed. [JEE]

An Electromyographic Analysis of the Knee During Functional Activities. I. The Normal Profile. Ciccotti MG, Kerlan RK, Perry J, Pink M. Reprinted from *Am J Sports Med* 22:645–650, 1994.

This study describes the fine-wire electromyographic profile of the normal knee. Twenty-two subjects with no prior history of knee injury volunteered for the study. Each subject had fine-wire electromyographic evaluation of 8 muscles (vastus medialis oblique, vastus lateralis, rectus femoris, semimembranosus, biceps femoris, tibialis anterior, gastrocnemius, and soleus muscles) while performing 7 functional activities. The percentage of maximum manual test for each muscle during each phase of the activities was used to determine means and standard deviations for the group. Walking and ramp and stair ascending and descending produced similar electromyographic profiles. Running and cross-cutting demonstrated unique electromyographic profiles with an overall higher muscle activity that the previous 5 activities. A quadriceps-hamstrings muscles' coordinated response was identified consistently in each activity. These findings illustrate the integral nature of each of the 8 examined muscles in knee motion. Furthermore, this study demonstrates a coordinated response of quadriceps-hamstrings muscles in the normal knee and may more thoroughly define the coordinated activity of these 2 antagonist muscle groups. Finally, this study provides a framework within which various knee conditions can be compared and from which specific rehabilitation recommendations can be generated. [JEE]

Flexibility of the Spine: Normative Values of Goniometric and Tape Measurements. Alaranta H, Hurri H, Heliovaara M, et al. Reprinted from *Scand J Rehabil Med* 26:147–154, 1994.

A sample of 508 male and female white-collar and blue-collar employees aged 35 to 54 years were examined clinically to determine the reliability of spinal flexibility measurements using inclinometers and a tape measure, and to determine the normal values of cervical sagittal movements, lateral flexion, lumbar flexion and extension, trunk rotation and sidebending. Spinal flexibility decreased with advancing age, particularly among the blue-collar workers. Male predominance was observed in lumbar flexion and rotation and female predominance in cervical flexion-extension-movement. Spinal flexibility was negatively related to the experience of disabling pain. The strongest connections were between cervical flexion-extension-movement and neck pain, and between trunk sidebending and low back pain during the preceding year. The interobserver reliabilities were found to be generally good for all these measurements, and trunk sidebending showed the highest reliability coefficients. The intraobserver reproducibility (checked at a one-year interval) was acceptable only for cervical flexion-extension movement, cervical sidebending and trunk sidebending. [JEE]

Interrater Reliability of the 7-Level Functional Independence Measure (FIM). Hamilton BB, Laughlin JA, Fiedler RC, Granger CV. Reprinted from *Scand J Rehabil Med* 26:115–119, 1994.

The Functional Independence Measure (FIM) is an 18-item, 7-level scale developed to uniformly assess severity of patient disability and medical rehabilitation functional outcome. FIM interrater reliability in the clinical setting is reported here. Clinicians from 89 US inpatient comprehensive medical rehabilitation facilities newly subscribing to the uniform Data System for Medical Rehabilitation from January 1988–June 1990 evaluated 1018 patients with the FIM. FIM total, domain and subscale score intraclass correlation coefficients (ICC) were calculated using ANOVA; FIM item score agreement was assessed with unweighted Kappa coefficient. Total FIM ICC was 0.96; motor domain 0.96 and cognitive domain 0.91; subscale score range: 0.89 (social cognition) to 0.94 (self-care). FIM item Kappa

range: 0.53 (memory) to 0.66 (stair climbing). A subset of 24 facilities meeting UDSMR data aggregation reliability criteria had Intraclass and Kappa coefficients exceeding those for all facilities. It is concluded that the 7-level FIM is reliable when used by trained/tested inpatient medical rehabilitation clinicians. [JEE]

Optimal Control for an Above-Knee Prosthesis with Two Degrees of Freedom. Popović D, Oguztoreli MN, Stein RB. Reprinted from *J Biomech* 28:89–98, 1995.

Our previous research and clinical tests of a self-contained powered above-knee prosthesis (AKP) showed that a knee joint with one degree of freedom (DOF) increases the energy cost of walking with respect to able-bodied subjects. Better symmetry of the gait can improve performance, so we suggest here the integration of a second powered DOF into the knee joint mechanism to control the internal-external rotation of the shank-foot complex. The control for the AKP with two DOFs is based on a method of optimal tracking. The data used for analysis were collected in able-bodied subjects braced with an ankle splint to experimentally duplicate a gait like that of amputees using a two-DOF prosthesis. The simulation showed the following: (1) the technique of optimal programming can be used for simulation of the artificial leg during locomotion; (2) the optimal tracking method is an efficient tool for selection of actuators for the above-knee prosthesis, ensuring that the tracking remains within limits. Limitation of joint torque is desirable in order to reduce the size of the motor, but beyond a certain point limiting maximal torques lead to tracking errors that are associated with higher energy costs and hence the need for a larger power source. The errors are also associated with higher forces at the interface between the socket and the prosthesis. The optimal tracking method allows the optimization of tracking with constraints on the size of the motor used and its energy cost. [JEE]

The Pain Disability Index: Factor Structure and Normative Data. Chibnall JT, Tait RC. Reprinted from *Arch Phys Med Rehabil* 75:1082–1086, 1994 (©1994 by the American Congress on Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation).

The factor structure and normative data for the Pain Disability Index (PDI) were examined in a large (N = 1,059) sample of chronic pain patients. The results support a one-factor solution for the PDI. Analyses of normative data indicated very small effects associated with gender, age, and pain duration. Relatively larger effects were associated with compensation status, litigation status, and circumstances of pain onset. Working patients reported less disability than their nonworking counterparts, litigating patients reported more disability than nonlitigants, and patients injured at work reported higher levels of disability than those with pain origins unrelated to work. The results reflect the disability level of patients referred to a hospital-based pain management program and may be useful as a reference point when comparing disability levels of other patient groups or research samples. [JEE]

Physiological Costs of Reciprocal Gait in FES Assisted Walking. Winchester P, Carollo JJ, Habasevich R. Reprinted from *Paraplegia* 32:680–686, 1994.

This study reports the velocity and physiologic cost index (PCI) of ambulation using a functional electrical stimulation (FES) system for ambulation in paraplegic spinal cord injured subjects. Using established techniques, average velocity and heart rate (HR) were measured on five subjects trained with the Parastep® system. PCI was reported for the four subjects who achieved a steady state during ambulation with the Parastep® system. It was found that walking performance varied greatly between subjects, and was correlated to frequency of use of the system. Velocity of walking with the Parastep® system ranged from 4.6 to 24.3 m/min. In the four subjects where steady state was achieved, PCI ranged from 2.30 to 6.26 beats/m. The average walking speed and PCI were similar to the values reported using alternative mechanical or hybrid systems available to the spinal cord injured for restoration of upright locomotion. [JEE]

Quantitative Analysis of Rising from a Chair in Healthy and Hemiparetic Subjects. Hesse S, Schauer M, Maalezic M, et al. Reprinted from *Scand J Rehabil Med* 26:161–166, 1994.

In 15 healthy and 20 hemiparetic persons we studied standing-up by two force-plates. Phases before and after the seat-off, force distribution and centre of gravity displacement were assessed. The patients rose significantly slower. The force ratios after seat-off differed significantly between the groups (0.88 vs 0.68). Left/right hemiparetic patients put more weight on the affected limb in 18%/11% of the trials before seat-off, with its insufficient use after it mainly in the left patients. At seat-off, projection of the

centre of gravity fell within the support area in hemiparetic patients, and 3 cm behind it in healthy subjects. With larger lateral displacement of the centre of gravity in the hemiparetic group, left hemiparetic patients mostly shifted their weight to the non-affected side and right hemiparetic patients to both sides. Weight distribution and mediolateral displacement of the centre of gravity in the left and right hemiparetic patients were considered. [JEE]

Restoration of Gait in Nonambulatory Hemiparetic Patients by Treadmill Training with Partial Body-Weight Support. Hesse S, Bertelt C, Schaffrin A, et al. Reprinted from *Arch Phys Med Rehabil* 75:1087–1093, 1994 (©1994 by the American Congress on Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation).

The effect of a treadmill training with partial body-weight support was investigated in nine nonambulatory hemiparetic patients with a mean poststroke interval of 129 days. They had received regular physiotherapy within a comprehensive stroke rehabilitation program at least 3 weeks before the treadmill training without marked improvement of their gait ability. After 25 additional treadmill training sessions scoring of functional performance and conventional gait analysis showed a definite improvement: gait ability, assessed by the Functional Ambulation Category (0 to 5) improved with a mean of 2.2 points, other motor functions, assessed by the Rivermead Motor Assessment Score with a mean of +3.9 points for gross function (range 0 to 13) and of +3.2 points for leg and trunk section (range 0 to 10) and gait cycle parameters ($p < .01$). Muscle tone and strength of the paretic lower limb remained stable. We suggest that treadmill training with partial body-weight support could augment restoration of ambulation and other motor functions in hemiparetic patients by active and repetitive training. [JEE]

Restoration of Gait with Orthoses in Thoracic Paraplegia: A Multicentric Investigation. Lotta S, Fiocchi A, Giovannini R, et al. Reprinted from *Paraplegia* 32:608–615, 1994.

Twenty-eight patients with complete T3-12 traumatic paraplegia were fitted with hip guidance orthosis (HGO, four cases), reciprocating gait orthosis (RGO, 13 cases) or advanced reciprocating gait orthosis (ARGO, 11 cases). Patients were enrolled for 2 months–6 years (median 5 months) in six Italian rehabilitation centres engaged in a common prospective protocol, including a 6 month follow up. After 12-84 (median 20) rehabilitation sessions over a 3–16 week (median 7) period of specific training all of the patients could perform don-doff manoeuvres autonomously in 2.5–15 min (median 6.4), and could walk at least 30 m with a walker (15 cases) or forearm crutches (13 cases) at 10–50 cm/s (median 16.6). HGO patients tended to walk more slowly than the others. None of them could walk upstairs, while three out of 13 RGO patients and seven out of 11 ARGO patients could. Six months later, 21 patients still used the orthosis for 0.5-3 h daily (median 2). Only four patients used the orthosis to walk outdoors. As a median they could still attain the speed recorded at discharge. Six patients had decided to abandon the device, while one was wheelchair bound due to a recent spinal intervention. Neither clinical, demographic or locomotor variables, nor centre and type of orthosis appeared to be predictive of abandonment of the device. During either the training or the follow up periods, six out of 14 RGO and seven out of 11 ARGO had repaired by the orthotist 1–10 times (median 3). Thus, in our sample of paraplegics, walking with these orthoses appeared to be a promising form of exercise rather than an alternative to wheelchair locomotion. [JEE]

The Use of Silicone Suspension Sleeves with Myoelectric Fittings. Salam Y. Reprinted from *J Prosthet Orthot* 6:119–120, 1994.

The use of silicone sleeves is very common in lower-extremity prosthetics (1,2,3). These sleeves, whether custom fabricated or off-the-shelf [a,b] provide suction suspension when used with a shuttle lock [b] system (see Figure 1). The use of these suspension methods for upper-extremity myoelectric prosthetics is described here. [JEE]

Visual Assessment of Hemiplegic Gait Following Stroke: Pilot Study. Hughes KA, Bell F. Reprinted from *Arch Phys Med Rehabil* 75:1100–1107, 1994 (©1994 by the American Congress on Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation).

A form that will guide clinicians through a reliable and valid visual assessment of hemiplegic gait was designed. Six hemiplegic patients were filmed walking along an instrumented walkway. These films were shown to three physiotherapists who used the form to rate the patients' gait. Each physiotherapist rated the six patients at both stages of recovery, repeating this a further two times. This resulted in 108 completed forms. Within-rater reliability is

statistically significant for some raters and some individual form sections. Between-rater reliability is significant for some sections. Detailed analysis has shown that parts of the form have caused reduced reliability. These are mainly sections that ask for severity judgments or are duplicated. Some indication of normal gait should be included on the form. To test validity fully the form should be tested on a group of patients who all have significant changes in each objective gait measurement. [JEE]

COMMUNICATION AIDS—REHABILITATION

Aging, Hearing Loss, and Hearing Aids: Myths Revisited. Thompson ME. Reprinted from *Am Rehabil* 19(4):20–24, 1993–94.

Reviews various studies that, one way or the other, ask the question, Why does such a small portion of elderly persons with impaired hearing use hearing aids? Among the answers are that some elderly people regard wearing a hearing aid as a sign of growing feeble, some have had inferior aids, other failed to get early intervention, and still others have not understood the benefits of improved hearing. [JDS]

Causes of Emotional and Psychological Reactions to Adventitious Blindness. Hudson D. Reprinted from *J Visual Impairm Blindn* 88:498–503, 1994.

From a review of 27 studies of social and psychological influences on the reactions to adventitious blindness. Fifteen regarded social factors as the primary causes, four personal factors, and eight a combination of the two. The author concludes that rehabilitation agencies should pay greater attention to social determinants of reactions to blindness and makes several suggestions by which they can improve their rehabilitation programs. [JDS]

The Concept of Adjustment: A Structural Model. Dodds A, Ferguson E, Ng L, et al. Reprinted from *J Visual Impairm Blindn* 88:487–498, 1994.

The Royal National Institute of the Blind studied 469 clients, aged 21–48 years, using The Nottingham Adjustment Scale and seven questionnaires that assessed general health, self-esteem, attitudes to blindness, locus of control, acceptance of disability, self-efficacy, and attributional style. LISREL analysis led to an adjustment model that seems to contradict the learned-helplessness concept and the notion that depression is mediated through expectancies for control. The authors recommend that counselors adopt cognitive and ratio-emotive therapies, rather than grief therapy. [JDS]

The Earth is Round ($p < .05$). Cohen J. Reprinted from *Am Psychologist* 49:997–1003, 1994.

Attacks the "ritual of null hypothesis significance testing." He recommends reporting effect sizes in terms of confidence intervals. He urges scientists in the 'soft' disciplines to rely more heavily on replication for validation. [JDS]

Ethics Education for Speech-Language Pathologists and Audiologists. Pannbacker MH, Middleton GF, Lass NJ. Reprinted from *Asha* 36(9):40–43, 1994.

Offers a model for ethics education, covering objectives, content, and an appendix of applicable terms. [JDS]

Intelligibility and Nonspeech Orafacial Strength and Force Control Following Traumatic Brain Injury. McHenry MA, Minton JT, Wilson RL, Post YV. Reprinted from *J Speech Hear Res* 37:1271–1283, 1994.

How do nonspeech orofacial strength and force control affect speech production after traumatic brain injury? The speech intelligibility of 11 males and 9 females was assessed by the CAIDS sentence test and force and strength by a variety of procedures. Only the 2 Newton (N) force level significantly correlated with intelligibility: the less-intelligible group sustained lower forces of the tongue at the 2N level than the more-intelligible group. However, as recognized by the investigators, the small number of subjects and the large number of variables simultaneously being probed tends to obscure relationships, encouraging statistical artifacts. As a pilot effort, this study may provoke more intensive research. [JDS]

Perceptual Rankings of Speech Quality Produced with One-Way Tracheostomy Speaking Valves. Leder SB. Reprinted from *J Speech Hear Res* 37:1308–1312, 1994.

Listeners judged taped speech of five adults who used four different one-way tracheostomy speaking valves: Kistner, Montgomery, Olympic, and Passy-Muir. Speech quality with the Montgomery and Passy-Muir valves ranked significantly higher than with the other two, and the Olympic significantly outranked the Kistner. [JDS]

Prediction of Asymptotic Threshold Shift Caused by Hearing Aid Use. Macrae JH. Reprinted from *J Speech Hear Res* 37:1450–1458, 1994.

Following earlier studies by the same investigator that show that temporary threshold shift as a result of hearing aid use can be predicted from a mathematical model, this paper warns that real-ear insertion gains (REIG) that exceed National Acoustical Laboratories' recommendations by 15 dB will be unsafe for persons with pure-tone averages greater than 80 dB HL. If such individuals want such REIG, they should avoid high ambient noise levels to escape permanent threshold shifts. [JDS]

Psychoneuroimmunology. Maier SF, Watkins LR, Fleshner M. Reprinted from *Am Psychologist* 49:1004–1017, 1994.

To describe interactions between behavior, brain, and immune system, the authors have coined the term psychoneuroimmunology. They review 98 publications, and conclude that "the immune system and brain form a bi-directional interacting set of processes, each regulating the other." They stress the necessity for interdisciplinary research to advance our understanding of the complexity of these relations. [JDS]

BOOK REVIEWS

Jerome D. Schein
Professor Emeritus of Sensory Rehabilitation, New York University, New York, NY

Comparative Studies in Special Education, edited by Kas Mazurek and Margaret A. Winzer. Washington, DC: Gallaudet University Press, 1994, 477 pp.

The 26 nations whose special education programs and policies are summarized in this book are assigned to five categories by the degree to which those programs and policies have been developed: Limited, Emerging, Segregated, Approaching Integration, and Integrated. The categorization seems to reveal the editors' bias with respect to placement of students with disabilities, favoring integration. However, in their introduction, they present an imposing list of factors that inhibit and facilitate special education. None of either refers specifically to the placement issue. Instead of a limited argument about a single issue, the book strives to advance its comparative studies as a means to improving special education through assembling a diverse data base, examining cultural influences, and observing the consequences of various academic administrative strategies.

The shortest way of conveying the breadth of the sample is to list the countries, in the order of their development, as determined by the editors: South Africa, Papua New Guinea, Senegal, West Bank and Gaza Strip, Nigeria, Islamic Republic of Iran, Brazil, Indonesia, Egypt, Pakistan, China, India, Uruguay, Japan, Taiwan, Russia, Czechoslovakia, Hong Kong, Israel, Poland, Australia, Canada, Finland, Norway, and Sweden, United States, New Zealand, and England and Wales.

The report from each country follows an outline calling for (*a*) prevalence, (*b*) methods of identification, (*c*) labeling, (*d*) social context, (*e*) legal and bureaucratic structure of special education, (*f*) teachers, schools, curriculum, and pedagogy, (*g*) major controversies, and (*h*) emerging trends. The editors are not specific about how they selected the authors of each section. They were "experts in special education who were themselves residents of and active professionals within the educational systems of the nations they wrote about." That they may not be representative of special educators in their countries and have their own agendas to pursue is the risk the editors chose to take. Bearing that in mind, readers may wish to know who the editors are. Both are professors of education at the University of Lethbridge, Canada. Mazurek lectures on comparative education, contemporary issues, and history of education. Winzer teaches courses in special education and educational psychology. She is the author or co-author of five other books.

Twenty-six selections are too many for individual critiques. Several had remarkable statements—one might even say errors. The one on the United States dates special education in the late nineteenth century, ignoring the founding of the first school for deaf students, at Hartford, Connecticut, in 1816. In the New Zealand report, Van Asch College is not mentioned, though it pioneered education for deaf students in that country. The chapter on Finland, Norway, and Sweden does not discuss the latter country's remarkable decision to educate deaf children in Swedish sign language. Were this reviewer more knowledgeable about other nations, the errors, and omissions would probably mount. Does that mean this book should not be read? Hardly, the wealth of material and its systematic placement (usually) within each chapter will repay the reader's investment of time handsomely. However, no reader should be misled—nor do the editors intend to mislead them—into believing that the individual chapters represent a consensus of special educators in that nation. With conditions changing so rapidly, readers can look forward to the next edition of this comprehensive document—one that will continue to contrast approaches to special education within and between nations.

The Deaf Community In Israel. Israel Sela and Amatzia Weisel. Hebrew text; English summary. Tel Aviv, Israel: Ministry of Labour and Social Affairs, 1992, 122 pp.

This monograph portrays the Israeli deaf community, based on a sample of 384, 18 to 85 years of age, residing in households. In accordance with most previous random samples of deaf people, the survey found the male-to-female ratio was 125:100. Fifty-seven percent of the sample were under 45 years of age, which closely approximates the average age of the general Israeli population. Based on self-reports, 84 percent considered themselves as having great difficulty hearing or not hearing at all, and 80 percent had a prelingual age at onset (before 3 years of age). Four in 10 had hearing aids, with the percentage declining as age increased.

Nearly one fourth of the sample did not complete elementary school; less than 30 percent had a high school education; and 7 percent had some higher education. The sample's unemployment rate was 37.5 percent. Almost two-thirds of the sample never received a promotion from their entry job. Most of the sample used sign language, and 60 percent rated their knowledge of sign "good" or "very good."

The trend toward deaf-by-deaf marriages was lower in Israel (75 percent) than in most U.S. samples (90 percent). Compared to the general population, more deaf people were single. About half of the sample members were affiliated with the Deaf Association.

While the bulk of the monograph is in Hebrew, those who do not know that language will find the English summary and the tabulated data make this document at least partially accessible. Because it is such a rich source of information, it will fully repay the effort to understand its entire contents, of which the above is only a small portion.

Deaf History Unveiled, edited by John V. Van Cleve. Washington, DC: Gallaudet University Press, 1993, 301 pp. Illustrated.

With one or two exceptions, the essays in this collection were prepared for the First International Conference on Deaf History in 1991. Amazing as it may seem, a conference held only a few years ago could be legitimately called "the first" such ever held. That it was, evidences the social suppression of deaf people, not only in the United States, but throughout the world. Whether viewed as a disabled minority or, as deaf people would prefer, as a linguistic and cultural minority, they have managed to create remarkable social structures within the countries where they live. Referred to in the singular as the Deaf Community, these manifestations of self-help deserve to be placed before all who wish to plan *for* rather than *with* disabled people.

This collection assembles delightfully written, inherently interesting glimpses at deaf people at numerous points in time, in several countries, and with renowned and little-known figures in a variety of activities. The two earliest essays deal with Pedro Ponce de Leon, during the second halt of the 16th century, and Abbé de l'Epée, during the 18th century—both well-known figures. Henri Gaillard's name is not likely to spark glints of recognition in many eyes, though it should; he struggled hard, at the end of the 19th century, for the rights of his deaf colleagues. Among the topics covered are: vocational education, education, publishing, and cochlear implants. Essays describe deaf affairs in Canada, Hungary, Italy, and Russia. Clearly, this is a volume not to be missed, either by those involved in any aspect of rehabilitation and those simply desiring 'a good read.'

Independence without Sight or Sound. Dona Sauerburger. New York: American Foundation for the Blind, 1993, 194 pp. Illustrated.

Subtitled "Suggestions for practitioners working with deaf-blind adults," this text focuses on orientation and mobility (O&M). The author has had two decades or more of experience as an O&M instructor, and she is unstinting in her willingness to share her experiences, the good and the embarrassing. Four of the nine chapters are devoted to communication. Psychology—isolation, assertiveness, and so forth—is discussed from the O&M instructor's viewpoint. The specifics of gaining adequate mobility take up the remainder of the book. In addition, it contains several helpful appendices and a 61-item list of references. The illustrations are excellent, but the typeface and narrow margins make the text hard on the eyes. That will not deter serious students from acquiring the book and profiting from its contents, because it is in all other respects worthwhile.

Missing Words. The Family Handbook on Adult Hearing Loss. Kay Thomsett and Eve Nickerson. Washington, DC: Gallaudet University Press, 1993, 243 pp.

This is a book for audiologists and otologists to give to patients newly diagnosed with impaired hearing. It opens with the personal account of Nickerson's progressive hearing loss, a condition that eventually forced her out of her position as a school teacher. Her co-author and daughter, Kay Thomsett, is a writer and editor in the Department of Veterans Affairs. Together, mother and daughter have prepared an easy-to-read guide for persons whose loss of hearing occurs in adulthood. Their information and suggestions for managing the typical, trying situations that confront hard of hearing people are supplemented with sidebars written by Donald H. Holden, an otologist in private practice. In addition to reading it themselves, hard of hearing people might want to give the book to family members, with the hope that they will develop greater empathy and, at the same time, learn some things they can do to ease the communication impasses that too often arise in households.

No Walls of Stone. An Anthology of Literature by Deaf and Hard of Hearing Writers, edited by Jill Jepson. Washington. DC: Gallaudet University Press, 1992. Illustrated. $19.95.

Yet another way of banishing the 'deaf and dumb' stereotype is to examine the writing of deaf authors. Readers will leave this collection buoyed by magnificent poems, stories, essays, and a one-act play, and buoyed even higher by the fact that all of the authors are deaf or hard of hearing. Most have not produced their work for any other reason than that they had something to tell. What they tell us, for the most part, is not morbid, though some of the pieces are angry. They are not weighted down by sorrow, but rather they are defiant, courageous, frustrated, realistic, hopeful, confident, and loving. They express all of the emotions that any other publication expresses. Once into the collection, most readers will have forgotten about the authors' hearing as they savor the work—which is as it should be. Rehabilitators will come away with many quotes, and many insights that will brighten their workdays and enhance their writing. For anyone tempted to brush aside a patient's complaint about ringing in the ears, the short poem "Tinnitus" will convert them from its opening lines, "It's more than just a lack/ of sound, you see,/ mere silence wouldn't give me/ so much trouble!" (p. 199) In clarifying the book's title, its editor remarks, "Even the experience of deafness has been likened to the materials from which walls are built: stone deaf, deaf as a post.... We have no choice now but to break down the barriers that separate us. At this time in history, we can no longer live with walls" (p. 13).

Understanding Deafness and the Rehabilitation Process, edited by Richard C. Nowell and Laura E. Marshak. Boston: Allyn & Bacon, 1994. 304 pp.

While the editors seek to help readers understand deafness and people who are deaf, they recognize the plethora of books on the subject already available and choose to concentrate on "the means by which deaf people make the transition from school to work, resolve personal and family situations, receive appropriate guidance, find and obtain access to appropriate jobs, and receive appropriate support to succeed in those jobs" (p. ix). They assay those objectives in 12 chapters by 18 authors.

The book begins with a brief orientation followed by three chapters that review affective, social, cognitive, language, and communication developments. Transition from school to independent living precedes chapters on assessment and work adjustment. Cognitive-behavioral psychotherapy is then considered in one chapter and systemic rehabilitation in another, while some legal issues are discussed in one chapter and acquisition of employment in a fourth.

Howard E. Stone, Jr., director emeritus of Self Help for Hard of Hearing People, and T. Alan Hurwitz, associate vice-president of the National Technical Institute for the Deaf, have prepared a useful disquisition on the various means by which persons with impaired hearing can overcome communication barriers. They describe telecommunication devices and strategies now available: teletypewriters or text telephones, computers, relay systems, captioned television, and telephone amplifiers. Hearing aids are thoroughly covered, with references including vibrotactile as well as the broad range of amplifiers, and a separate section on alarms and alerting devices. They present four categories of assistive listening systems for auditoriums and meeting rooms. They offer suggestions for normally hearing persons to follow in improving communication with deaf and hard of hearing persons. Very importantly, they discuss in depth the use of oral and sign-language interpreters. Not only do they provide information about interpreter preparation, ethical issues, and related matters, but also they offer guidelines for effective use of interpreters, particularly in counseling.

The editors realize some of the difficulties in assembling a text on so many diverse topics, each written by different authors. Given the editors' professional backgrounds, this reviewer would have preferred the book they could have written by themselves. As it stands, however, this edited volume maintains throughout a favorable rehabilitation posture—one expressing the belief that "Deaf people are truly 'differently abled' and not disabled" (p. x)

A Picture of Health. Statistics New Zealand and Ministry of Health. Wellington, New Zealand: Authors, 1993, 161 pp.

Based on a stratified random sample of 7,000 New Zealand households, this survey, conducted from April, 1992, to March, 1993, reports extensive data on health-related issues. For those who have had the pleasure of visiting or living on these two scenically magnificent islands, it will come as a surprise to find that one-third of the respondents said they have a long-term illness or disability. Yet only 10 percent rated their health "not so good" or "poor." (This being the first such national study conducted, unpacking these somewhat contradictory findings will doubtless be the subject of future surveys.) Older persons, persons out

of the labor force, Maoris and other Pacific Islanders, and poor people were least likely to rate their health "good" or "excellent." In the previous year, one-fourth of the sample had been in the hospital, and 70 percent had one or more prescriptions filled.

Life expectancy of male New Zealanders is 71.9 years and of females, 78.0 years. The comparable figures for the United States are 71.6 for males and 78.6 for females. New Zealand's neighbor, Australia, projects 73.2 for males and 79.8 for females. The leading causes of death are coronary heart disease, cancer, and stroke. These three account for 61 percent of deaths in Now Zealand.

New Zealanders do not take advantage of their salubrious climate and inviting outdoors. More than half had no vigorous exercise in the preceding week of the survey. Those who did rated their health "excellent" more often than those who did not. About one in four adults smokes, and of those 15 years and older, over half had consumed an alcoholic beverage in the past week. About 28 percent of those 15 years and older were classified as obese, while 11 percent were judged underweight.

These are a few of the highlights from this survey. Based on these results, it is most likely that the New Zealand government, like the U.S. government, will opt for annual surveys to determine the nation's health. The full value of such studies comes from observing trends, which emerge as each year's data are added to the previous years. Also, puzzling and unusual findings can be unraveled as subsequent surveys target particular groups or add questions to tease out their meaning.

PUBLICATIONS OF INTEREST

This list of references offers *Journal* readers significant information on the availability of recent rehabilitation literature in various scientific, engineering, and clinical fields. The *Journal* provides this service in an effort to fill the need for a comprehensive and interdisciplinary indexing source for rehabilitation literature.

All entries are numbered so that multidisciplinary publications may be cross-referenced. They are indicated as *See also* at the end of the categories where applicable. A listing of the periodicals reviewed follows the references. In addition to the periodicals covered regularly, other publications will be included when determined to be of special interest to the rehabilitation community. To obtain reprints of a particular article or report, direct your request to the appropriate contact source listed in each citation.

Page **List of Categories**

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Listings #30 through #53 have been collected for this section by Gregory L. Goodrich, PhD. VA Western Blind Rehabilitation Center, Palo Alto, CA.

A Literature search was conducted using the keyword citation index of Low Vision—The References edited by Gregory L. Goodrich, PhD and Randy T. Jose, OD. Published by the Lighthouse Inc., New York, NY.

Because these listings are extracted from several databases, we lack *Contact* information. If more information is needed, the author may be contacted in care of the publisher of the journal or book in which the article appears.

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Contact: Stefan Hesse, MD, Dept. of Neurological Rehabilitation, Free University Berlin, Klinik Berlin, Berlin, Germany

FUNCTIONAL ELECTRICAL STIMULATION

57. Implant Provision of Key, Pinch and Power Grips in a C6 Tetraplegic. Perkins TA, et al., *Med Biol Eng Comput* 32(4):367–372, 1994.
Contact: T.A. Perkins, MRC Neurological Prostheses Unit, 1-2 Windsor Walk, London SE5 8BB, UK

58. Physiologic Costs of Reciprocal Gait in FES Assisted Walking. Winchester P, Carollo JJ, Habasevich R, *Paraplegia* 32(10):680–686, 1994.
Contact: P. Winchester PhD, PT, Mobility Research and Assessment Laboratory, University of Texas Southwestern Medical Center, Dallas, TX 75080

GAIT ANALYSIS

59. Energy Expenditure of Trans-Tibial Amputees during Ambulation at Self-Selected Pace. Gailey RS, et al., *Prosthet Orthot Int* 18(2):84–91, 1994.
Contact: Robert S. Gailey, University of Miami, Division of Physical Therapy, 5th Floor Plumer Bldg., 5915 Ponce de Leon Blvd., Coral Gables, FL 33146

60. Evidence of Interaction Between Human Lumbosacral and Cervical Neural Networks during Gait. Eke-Okoro ST, *Electromyogr Clin Neurophysiol* 34(6):345–349, 1994.
Contact: S.T. Eke-Okoro, Dr.Med.Sc., Dept. of Medical Rehabilitation, College of Medicine, University of Nigeria, Enugu Campus, Nigeria

61. Gait in Male Trans-Tibial Amputees: A Comparative Study with Healthy Subjects in Relation to Walking Speed. Hermodsson Y, et al., *Prosthet Orthot Int* 18(2):68–77, 1994.
Contact: Y. Hermodsson, Dept. of Orthopaedics, Helsingborg Hospital, S-251 87 Helsingborg, Sweden

62. Hip and Ankle Walking Strategies: Effect on Peak Plantar Pressures and Implications for Neuropathic Ulceration. Mueller MJ, et al., *Arch Phys Med Rehabil* 75(10):1196–1200, 1994.
Contact: Michael Mueller, PhD, Program in Physical Therapy, 660 South Euclid Ave., Box 8502, St. Louis, MO 63110

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Contact: Mark S. Redfern, PhD, Rm. 127, EEI, 203 Lothrop St., Pittsburgh, PA 15213

64. Restoration of Gait in Nonambulatory Hemiparetic Patients by Treadmill Training with Partial Body-Weight Support. Hesse S, et al., *Arch Phys Med Rehabil* 75(10):1087–1093, 1994.
Contact: Stefan Hesse, MD, Klinik Berlin, Kladower Damm 223, 14089 Berlin, Germany

65. Restoration of Gait with Orthoses in Thoracic Paraplegia: A Multicentric Investigation. Lotta S, et al., *Paraplegia* 32(9):608–615, 1994.
Contact: L. Tesio, MD, Divisione di Recupero e Rieducazione Funzionale, Unita Spinale, Vicenza, Italy

66. Step-Length Biofeedback Device for Walk Rehabilitation. Montoya R, et al., *Med Biol Eng Comput* 32(4):416–420, 1994.

Contact: R. Montoya, URA CNRS 649, Laboratoire de Physiologie, Faculte de Medecine de Toulouse, 133, Route de Narbonne, 31062 Toulouse Cedex, France

67. Temporal, Kinematic, and Kinetic Variables Related to Gait Speed in Subjects with Hemiplegia: A Regression Approach. Olney SJ, Griffin MP, McBride ID, *Phys Ther* 74(9):872–885, 1994.
Contact: Sandra J. Olney, PhD, School of Rehabilitation Therapy, Queen's University, Kingston, ON K7L 3N6, Canada
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GENERAL

68. Bomb-Related Injuries. Karmy-Jones R, et al., *Milit Med* 159(7):536–539, 1994.
Contact: R. Karmy-Jones, MD, FRCSC, Division of Trauma/SICU, Henry Ford Hospital, 2799 West Grand Blvd., Detroit, MI 48202–2689

69. Car Driving for the Severely Physically Disabled: The American Experience. Shand J, Sivewright JP, *Paraplegia* 32(10):697–699, 1994.
Contact: J. Shand, 9 Almond Court, Thistle Foundation, Edinburgh, Scotland

70. Critical Appraisal of the Quality of Quality-of-Life Measurements. Gill TM, Feinstein AR, *JAMA* 272(8):619–626, 1994.
Contact: Thomas M. Gill, MD, Yale University of Medicine, 333 Cedar St., 17 TMP, P.O. Box 208025, New Haven, CT 06520-8025

71. Simulated Neural Networks to Predict Outcomes, Costs, and Length of Stay Among Orthopedic Rehabilitation Patients. Grigsby J, Kooken R, Hershberger J, *Arch Phys Med Rehabil* 75(10):1077–1081, 1994.
Contact: Jim Grigby, PhD, Center for Health Services Research, 1355 South Colorado Blvd., #706, Denver, CO 80222

GERIATRICS

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Contact: Mary E. Tinetti, MD, 333 Cedar St., P.O. Box 208025, New Haven, CT 06520-8025

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Contact: K. Styrborn, Dept. of Geriatrics, Kungsgardet Hospital, University Hospital, Uppsala, Sweden

MUSCLES, LIGAMENTS, AND TENDONS

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Contact: G.V. Dimitrov, Bulg Acad Sci, CLBA, G. Bontchev Str., bl.105, 1113 Sofia, Bulgaria

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Contact: P.K. Kyberd, BSc, MSc, PhD, Oxford Orthopaedic Engineering Centre, University of Oxford, Nuffield Orthopaedic Centre, Headington, Oxford

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Contact: G.J.C. Ettema, Dept. of Antomical Sciences, The University of Queensland, Queensland 4072, Australia

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Contact: Prof. M. Solomonow, Bioengineering Laboratory, Dept. of Orthopaedic Surgery, Louisiana State University Medical Center, 2025 Gravier St., Suite 400, New Orleans, LA 70112
See also 11,16,61

MYOELECTRIC CONTROL

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Contact: Carlo J. DeLuca, NeuroMuscular Research Center, Boston University, Boston, MA 02215

NEUROLOGICAL DISORDERS

79. Inhibitory CA1-CA3-Hilar Region Feedback in the Hippocampus. Sik A, et al., *Science* 265:1722–1724, 1994.

Contact: Attila Sik, Dept. of Neurology, University of Kuopio, Finland

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Contact: Marcia Barinaga, c/o Science, P.O. Box 2033, Marion, OH 43305-2033

81. Tactile Sensory Impairments and Prehensile Function in Subjects with Left-Hemisphere Cerebral Lesions. Robertson SL, Jones LA, *Arch Phys Med Rehabil* 75(10):1108–1117, 1994.
Contact: Lynette A. Jones, PhD, Dept. of Medical Engineering, Room 3-148, MIT, 77 Massachusetts Ave., Cambridge, MA 02139

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Contact: Karen A. Hughes, BSc, Division of Physiotherapy, Glasgow Caledonian University, Glasgow, Scotland
See also 23,43,83

ORTHOPEDICS

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Contact: K.J. Drabu, FRCS, MBOA, Orthopaedic Research Unit, East Surrey Hospital, Redhill, Surrey

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Contact: Robert F. McLain, MD, Dept. of Orthopaedic Surgery, University of California-Davis, 2230 Stockton Blvd., Sacramento, CA 95817

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Contact: Harold B. Kitaoka, MD, Mayo Clinic and Mayo Foundation, 200 First Street S.W., Rochester, MN 55905

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Contact: Gary Weiner, MD, Dept. of Orthopaedic Surgery, Maricopa Medical Center, 2601 East Roosevelt St., Phoenix, AR 85008

87. Polyethylene Wear Debris and Tissue Reactions in Knee as Compared to Hip Replacement Prostheses. Schmalzried TP, et al., *J Appl Biomater* 5(3):185–190, 1994.
Contact: Thomas P. Schmalzried, MD, Joint Replacement Institute, 2400 S. Flower St., Los Angeles, CA 90007

88. Rheumatoid Arthritis of the Cervical Spine: Surgical Decision Making Based on Predictors of Paralysis and Recovery. Boden SD, *Spine* 19(20):2275–2280, 1994.
Contact: Scott D. Boden, MD, Emory University School of Medicine, The Emory Spine Center, 2165 North Decatur Road, 2165 North Decatur, GA 30033

89. Swedish Knee Arthroplasty Register: A Nation-Wide Study of 30,003 Knees 1976–1992. Knutson K, et al., *Acta Orthop Scand* 65(4):375–386, 1994.
Contact: Kaj Knutson, Dept. of Orthopedics, University Hospital, Lund, Sweden
See also 17

PROSTHETICS

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Contact: Dr. K.M. Patil, Dept. of Applied Mechanics, Bengal Engineering College, Howrah 711 103, West Bengal, India
See also 3,35

ROBOTICS and INDEPENDENT LIVING AIDS

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Contact: P. Potamianos, BSc, MSc, Dept. of Mechanical Engineering, Imperial College of Science, Technology and Medicine, London

SPINAL CORD INJURY

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Contact: Lawrence G. Lenke, MD, Dept. of Orthopaedics,

Washington University Medical Center, Suite 11300 West Pavilion, One Barnes Hospital Plaza, St. Louis, MO 63110

93. Comparison of Ultrasound/Ultraviolet-C and Laser for Treatment of Pressure Ulcers in Patients with Spinal Cord Injury. Nussbaum EL, Biemann I, Mustard B, *Phys Ther* 74(9):812–825, 1994.
Contact: Ethne L. Nussbaum, MEd, BSc(PT), Mount Sinai Hospital, Dept. of Physical Therapy, University of Toronto, 256 McCaul St., Toronto, ON M5T 1W5 Canada

94. Early Outcome in Cervical Spinal Cord Injured Patients Older than 50 Years of Age. Alander DH, Andreychik DA, Stauffer ES, *Spine* 19(20):2299–2301, 1994.
Contact: Dirk H. Alander, MD, Southern Illinois University, School of Medicine, Division of Orthopaedics and Rehabilitation, P.O. Box 19230, Springfield, IL 67294-9230

95. Ejaculation Induced by Penile Vibratory Stimulation in Men with Spinal Cord Injuries: The Importance of the Vibratory Amplitude. Sonksen J, Biering-Sorensen F, Kristensen JK, *Paraplegia* 32(10):651–660, 1994.
Contact: J. Sonksen, MD, Dept. of Urology, The National University Hosptial, Blegdamsvej 9, DK-2100 Copenhagen 1, Denmark

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Contact: Mindy L. Aisen, MD, The Burke Rehabilitation Center, 685 Mamaroneck Ave., White Plains, NY 10605

97. Gangrenous Cystitis in a Paraplegic Patient: Case Report. Hughes ODM, et al., *Paraplegia* 32(9):622–623, 1994.
Contact: O.D.M. Hughes, BM, BS, BSc, Senior House Officer in Urology, Dept. of Urology, Cardiff Royal Infirmary, Newport Rd., Cardiff CF2 1SZ Wales

98. Massive Steroids Do Not Reduce the Zone of Injury After Penetrating Spinal Cord Injury. Prendergast MR, et al., *J Trauma* 37(4):576–580, 1994.
Contact: Charles E. Lucas, MD, Dept. of Surgery, Room 45-13, Wayne State University, 4201 St. Antoine, Detroit, MI 48201

99. Single-Stage Reconstruction of Key Pinch and Extension of the Elbow in Tetraplegic Patients. Paul SD, et al., *J Bone Joint Surg* 76A(10):1451–1456, 1994.
Contact: Stephen D. Paul, MD, 8635 West 3rd St., 965W, Los Angeles, CA 90048

100. Use of Intracavernous Injection of Prostaglandin E1 for Neuropathic Erectile Dysfunction. Hirsch IH, et al., *Paraplegia* 32(10):661–664, 1994.
Contact: Irvin H. Hirsch, MD, Jefferson Medical College, Dept. of Urology, 1025 Walnut St., 11th Floor College Bldg., Philadelphia, PA 19107

101. Waist and Neck Enlargement After Quadriplegia. Frisbie JH, Brown R, *J Am Paraplegia Soc* 17(4):177–178, 1994.
Contact: Jamea H. Frisbie, MD, Spinal Cord Injury Service, DVA Medical Center, Brockton, MA 02401
See also 33,34,41

SURGERY

102. Replantation, Revascularization, and Reconstruction of Both Legs After Amputations: A Case Study. Tukianen E, et al., *J Bone Joint Surg* 76A(11):1712–1716, 1994.
Contact: Erkki Tukianinen, MD, Dept. of Plastic Surgery, Helsinki University Central Hospital, Topeliuksenkatu 5, SF-00260 Helsinki, Finland
See also 2

VOCATIONAL

103. Return to Work for Persons with Traumatic Brain Injury and Spinal Cord Injury: Three Case Studies. Wehman P, et al., *Int J Rehabil Res* 17(3):268–277, 1994.
Contact: Paul Wehman, Dept. of Physical Medicine and Rehabilitation, VCU Box 2011, Medical College of Virginia, Virginia Commonwealth University, Richmond, VA 23284

WHEELCHAIRS and POWERED VEHICLES

104. Automatic Clutch. Beck K, *Paraplegia News* 48(9):40, 1994.
Contact: Automotive Alert, c/o Karl Beck, Florida Sales Manager, The Braun Corporation, 5072 113th Ave. North, Clearwater, FL 34620

105. Determination of Gross Weight Limit for Foldaway Powered Wheelchairs Through Isometric and Psychophysical Strength Simulations. Mital A, *Ergonomics* 37(9):1549–1561, 1994.

Contact: Anil Mital, Ergonomics and Engineering Controls Research Laborabory, Dept. of Industrial Engineering, University of Cincinnati, Cincinnati, OH 45221-0116

106. Wheelchair Propulsion Efficiency: Movement Pattern Adaptations to Speed Changes. Vanlandewijck YC, Spaepen AJ, Lysens RJ, *Med Sci Sports Exerc* 26(11):1373–1381, 1994.
Contact: Yves C. Vanlandewijck, Dept. of Clinical Kinanthropology, Faculty of Physical Education and Physiotherapy, Katholieke Universiteit Leuven, Leuven, Belgium

107. Wheelchair-Related Accidents Caused by Tips and Falls Among Noninstitutionalized Users of Manually Propelled Wheelchairs in Nova Scotia. Kirby RL, et al., *Am J Phys Med Rehabil* 73(5):319–330, 1994.
Contact: R. Lee Kirby, MD, Division of Physical Medicine and Rehabilitation, Dept. of Medicine, Dalhousie University, c/o Nova Scotia Rehabilitation Centre, 1341 Summer St., Halifax, Nova Scotia, B3H 4K4, Canada

WOUNDS and ULCERS

108. Function of KGF in Morphogenesis of Epithelium and Reepithelialization of Wounds. Werner S, et al., *Science* 266:819–822, 1994.
Contact: Sabine Werner, Max-Planck-Institut fur Biochemie, Am Klopferspitz 18a, 82152 Martinsried, Germany
See also 38,73

Periodicals reviewed for PUBLICATIONS OF INTEREST

Acta Orthopaedica Scandinavica
Advances in Orthopaedic Surgery
American Journal of Occupational Therapy
American Journal of Physical Medicine and Rehabilitation
American Journal of Sports Medicine
American Rehabilitation
Annals of Biomedical Engineering
Archives of Physical Medicine and Rehabilitation
ASHA (American Speech and Hearing Association)
Assistive Technology
Biomaterials, Artificial Cells, and Immobilization Biotechnology
Biomedical Instrumentation & Technology
Canadian Journal of Rehabilitation
Clinical Biomechanics
Clinical Kinesiology
Clinical Orthopaedics and Related Research
Clinical Rehabilitation
CRC Critical Reviews in Biomedical Engineering
DAV Magazine (Disabled American Veterans)
Disability and Rehabilitation
Electromyography and Clinical Neurophysiology
Engineering in Medicine and Biology Magazine
Ergonomics
Hearing Journal
Hearing Rehabilitation Quarterly
Hearing Research
Human Factors: The Journal of the Human Factors Society
IEEE Engineering in Medicine and Biology Magazine
IEEE Transactions on Biomedical Engineering
IEEE Transactions in Systems, Man and Cybernetics
IEEE Transactions on Rehabilitatin Engineer
International Journal of Rehabilitation Research
JAMA
Journal of Acoustical Society of America
Journal of Applied Biomaterials
Journal of Biomechanical Engineering
Journal of Biomechanics
Journal of Biomedical Engineering
Journal of Biomedical Materials Research
Journal of Bone and Joint Surgery—American Ed.
Journal of Bone and Joint Surgery—British Ed.
Journal of Clinical Engineering
Journal of Electromyography and Kinesiology
Journal of Head Trauma and Rehabilitation
Journal of Medical Engineering and Technology
Journal of Neurologic Rehabilitation
Journal of Orthopaedic and Sports Physical Therapy
Journal of Orthopaedic Research
Journal of Prosthetics and Orthotics
Journal of Rehabilitation
Journal of Speech and Hearing Research
Journal of Trauma
Journal of Vision Rehabilitation
Journal of Visual Impairment and Blindness
The Lancet
Medical and Biological Engineering and Computing
Medical Psychotherapy Yearbook
Medicine & Science in Sports and Exercise
Military Medicine

New England Journal of Medicine
The Occupational Therapy Journal of Research
Orthopaedic Review
Orthopedic Clinics of North America
Orthopedics
Paraplegia
Paraplegia News
Physical and Occupational Therapy in Geriatrics
Physical Medicine and Rehabilitation
Physical Therapy
Physiotherapy
Proceedings of the Institution of Mechanical Engineers Part H: Journal of Engineering in Medicine
Prosthetics and Orthotics International
Rehab Management
Rehabilitation Digest
Scandinavian Journal of Rehabilitation Medicine
Science
Spine
Sports 'N Spokes
Techniques in Orthopaedics
Topics in Geriatric Rehabilitation
VA Practitioner
Vanguard
Volta Review

CALENDAR OF EVENTS

NOTE: An asterisk at the end of a citation indicates a new entry to the calendar.

1995

March, 1995
Vth International Conference for Surgical Rehabilitation of Upper Limb in Tetraplegia (Quadraplegia), Melbourne, Australia
Contact: Gerard Sormann, MBBS, FRACS, The Medical Centre, 517 St. Kilda Road, Melbourne 3004, Australia; Tel: +61+3-866-8668; Fax: +61+3-867-8637

March 21-25, 1995
American Academy of Orthotists and Prosthetists Annual Meeting (AAOP), New Orleans, Louisiana
Contact: Annette Suriani, 1650 King Street, Suite 500, Alexandria, VA 22314; Tel: 703-836-7116

March 23-25, 1995
4th International Muscle Symposium, Zurich, Switzerland
Contact: Manfred Frey, MD, Division of Hand, Plastic and Reconstructive Surgery, Department of Surgery, University of Zurich Medical School, Ramistrasse 100, CH-8091 Zurich, Switzerland; Tel: 41 1 255 2707; Fax: 41 1 255 4425*

March 27-31, 1995
12th World Congress of the International Federation of Physical Medicine and Rehabilitation (IFPMR), Sydney, Australia
Contact: Dianna Crebbin Conferences, PO Box 629, Willoughby NSW 2068, Australia; Tel: +61 (02) 417-8525; Fax: +61 (02) 417-8513

April 2-7, 1995
8th World Congress of the International Society for Prosthetics and Orthotics (ISPO), Melbourne, Australia
Contact: Congress Secretariat, 84 Queensbridge Street, South Melbourne, Victoria, Australia 3205; Tel: +61+3-682-0244; Fax: +61+3-682-0288

April 8-9, 1995
14th Southern Biomedical Engineering Conference, Shreveport, Louisana
Contact: Dr. Debi P. Mukherjee; Tel: 318-674-6187; Fax: 318-674-6186

April 8-12, 1995
The American Occupational Therapy Association, 1995 Annual Conference and Exposition, Denver, Colorado
Contact: 1995 Conference and Exposition, c/o AOTA, 4720 Montgomery Lane, PO Box 31220, Bethesda, MD 20824-1220; Tel: 301-652-AOTA; Fax: 310-652-7711*

April 9-11, 1995
Japanese Orthopaedic Association: 68th Annual Meeting, Yokohama City, Japan
Contact: Dr. T. Kurokawa, President, Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, 113, Japan

April 25-28, 1995
INTERHOSPITAL '95, Hannover, Germany
Contact: Donna Peterson Hyland; Tel: 609-987-1202; Fax: 609-987-0092

May 1-3, 1995 American Spinal Cord Injury Association Annual Meeting (ASIA), Orlando, Florida
Contact: ASIA; Tel: 404-355-9772

May 4-6, 1995
2nd International Workshop on Implantable Telemetry, Measurement of Mechanical Parameters in Humans, Berlin, Germany
Contact: Dr.-Ing. Georg Bergmann, Oskar-Helene-Heim, Biomechanics-Laboratory, Orthopaedic Hospital of the Free University, Clayallee 229, D - 14195 Berlin, Germany; Tel: Int. +49 30 81004-273; Fax: Int. +49 30 81004-207

May 5-6, 1995
6th Annual Meeting of Orthopaedic Rehabilitation Association, Denver, Colorado
Contact: Mary Bizzell, Executive Secretary, Orthopaedic Rehabilitation Association, c/o Sheperd Spinal Center, 2020 Peachtree Road, N.W., Atlanta, GA 30309*

May 27-31, 1995
1st International Rehabilitation Medicine Congress, Istanbul, Turkey

Contact: Dr. Onder Kayhan, Congress Secretariat, P.O. Box 1, Kosuyolo 81121, Istanbul, Turkey; Tel: (90) 216-326-4217; Fax: (90) 216-325-0323

May 28 - June 1, 1995
5th European Congress on Research in Rehabilitation, Helsinki, Finland
Contact: Professor Simon Miller, Division of Clinical Neuroscience, The Medical School, The University, Newcastle upon Tyne, NE2 4HH, United Kingdom; Tel: +44 91 222 6617; Fax: +44 91 222 8803

June 4-7, 1995
11th Annual Meeting, International Society of Technology Assessment in Health Care, Stockholm, Sweden
Contact: ISTAHC Congrex (Sweden) AB, PO Box 5619, S-114 86, Stockholm, Sweden*

June 9-14, 1995
RESNA International Conference Vancouver, BC
Contact: RESNA; Tel: 703-524-6686

June 22-25, 1995
Annual Meeting of the American Congress of Rehabilitation Medicine, Arlington, Virginia
Contact: American Congress of Rehabilitation Medicine, 5700 Old Orchard Road, First Floor, Skokie, IL 60077-1057; Tel: 708-966-0095; Fax: 708-966-9418

July 2-3, 1995
5th Conference European Orthopaedic Research Society, Munich, Germany
Contact: Dr. HP Scharf, Orthopaedische Klinik/RKU, Oberer Eselsberg 45, D-89081 Ulm, Germany; Tel: +49 731 177 513; Fax: +49 731 177 574*

July 2-6, 1995
XVth Congress of the International Society of Biomechanics, Jyvaskyla, Finland
Contact: XVth ISB Congress Secretariat, University of Jyvaskyla, Jyvaskyla Congresses, PO Box 35, Fin-40351 Jyvaskyla, Finland; INTERNET: tvanttin@yu.fi; Fax: +358 41 603621*

July 9-16, 1995
4th World Congress of Neuroscience, Kyoto, Japan
Contact: Host Organizer, Secretariat, 4th World Congress of Neuroscience, c/o International Communications, Inc., Kasho Bldg., 2-14-9, Nihonbashi, Chuo-ku, Tokyo 103, Japan; Tel: 81-03-3272-7981; Fax: 81-03-3273-2445

July 16-18, 1995
18th International Congress on Education of the Deaf, Jerusalem, Israel
Contact: Secretariat, 18th International Congress on Education of the Deaf/1995, PO Box 50006, Tel Aviv 61500, Israel*

July 16-19, 1995
7th International Conference on Mobility and Transport for Elderly and Disabled People, Reading, England
Contact: 7th International Conference Secretariat, Disability Unit, Department of Transport, Room S10/21, 2 Marsham Street, London SW1P 3EB, England

July 22-27, 1995
3rd International Neurotrauma Symposium, Toronto, Canada
Contact: Conference Secretariat c/o: Congress Canada, 191 Niagara Street, Toronto, Ontario, Canada, M5V 1C9; Tel: 416-860-1772; Fax: 416-860-0380

August 17-19, 1995
5th Vienna International Workshop on Functional Electrostimulation: Basics, Technology and Application, Vienna, Austria
Contact: Institute of Biomedical Engineering and Physics, Secretary: Ch. Jancik, Waehringer Guertel 18-20/4L, A-1090 Vienna, Austria; Tel: (+43-1)40400/1984; Fax: (+43-1)40400/3988; E-mail: M.BJAK@BMTP.AKH-WIEN.AC.AT*

September 5-7, 1995
41st Annual Conference of the American Paraplegia Society, Las Vegas, Nevada
Contact: Mario T. Balmaseda, Jr., MD, Program Committee Chairman, American Paraplegia Society, 75-20 Astoria Boulevard, Jackson Heights, NY 11370-1177*

September 5-8, 1995
2nd Leeds European Rehabilitation Conference Neurological Rehabilitation: New Initiatives in Treatment & Measuring Outcome, Leeds, England UK
Contact: Mrs. Carol Would, Conference Secretary, Department of Continuing Professional Education, Continuing Education Building, Springfield Mount, Leeds LS2 9NG; Tel: +44 (0532) 333232; Fax: +44 (0532) 333240

September 8-10, 1995
4th Scientific Meeting of the Scandinavian Medical Society of Paraplegia, Oslo, Norway
Contact: Congress Secretariat, 4th Scientific of SMSOP, c/o Sunnaas Hospital, N-1450 Nesoddtangen, Norway; Tel: +47 66 96 90 00; Fax: +47 66 91 25 76

September 11-13, 1995
First Biennial Conference, Advancing Human Communication: An Interdisciplinary Forum on Hearing Aid Research and Development, Bethesda, Maryland
Contact: NIDCD; Tel: 301-496-7243; TDD 301-402-0252

September 11-19, 1995
10th Asia Pacific Regional Conference of Rehabilitation International, Indonesia
Contact: Secretariat, 10th ASPARERI, H.Hang, jebat II-2 Blok F IV, Kebayoran Baru, Jakarta 12120, Indonesia; Tel: +62 21 717 366

September 19-23, 1995
American Orthotic and Prosthetic Association, National Assembly (AOPA), San Antonio, Texas
Contact: Annette Suriani, 1650 King Street, Suite 500, Alexandria, VA 22314; Tel: 703-836-7116

September 20-23, 1995
17th Annual International Conference of the IEEE Engineering in Medicine and Biology Society and 21st Canadian Medical and Biological Engineering Conference, Montreal, Canada
Contact: Robert E. Kearney, PhD, Eng, Department of Biomedical Engineering, McGill University, 3775 University Street, Montreal, Quebec, Canada H3A 2B4; Tel: 514-398-6737; Fax: 514-398-7461; E-Mail: rob@neuron.biomed.mcgill.ca

November 2-4, 1995
Annual Scientific Meeting of the International Medical Society of Paraplegia, New Delhi, India
Contact: The Secretariat, International Medical Society of Paraplegia, National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury, Bucks HP21 8AL, UK; Tel: 44 296 315866; Fax: 44 296 315286*

November 12-16, 1995
11th Congress of the Western Pacific Orthopaedic Association, Hong Kong
Contact: Professor SP Chow, Department of Orthopaedic Surgery, Queen Mary Hospital, Pokfulam, Hong Kong; Tel: 852 855 4258; Fax: 852 817 4392*

November 17-20, 1995
American Speech-Language-Hearing Association (ASHA), Annual Convention, Cincinnati, Ohio
Contact: Frances Johnston, ASHA, 10801 Rockville Pike, Rockville, MD 20852; Tel: (301) 897-5700

November 17-22, 1995
American Academy of Physical Medicine & Rehabilitation (AAPM&R), Orlando, Florida
Contact: AAPM&R; Tel: 312-922-9366

1996

February 22-27, 1996 American Academy of Orthopedic Surgeons Annual Convention (AAOS), Orlando, Florida
Contact: AAOS, 6630 North River Rd., Rosemont, IL 60018-4226; Tel: 708-823-7186; Fax: 708-823-8031

April 22-May 5, 1996
18th World Congress of Rehabilitation International Equality Through Participation—2000 and Beyond, Auckland, New Zealand
Contact: Mrs. Bice Awan, Accident Rehabilitation & Compensation, Insurance Corporation, PO Box 242, Wellington, New Zealand; Tel: +64 4 4738 775

May 12-16, 1996
The First Mediterranean Congress on Physical Medicine and Rehabilitation, Herzlia, Israel
Contact: Dr. Haim Ring, c/o Ortra Ltd., PO Box 50432, Tel Aviv 61500, Israel; Tel: 972-3-664825; Fax: 972-3-660952

August 7-10, 1996
7th International ISAAC Conference on Augmentative and Alternative Communication, Vancouver, BC, Canada
Contact: ISAAC, PO Box 1762, Station R., Toronto, Ontario, Canada; Tel: +1 416 737 9308

August 16-27, 1996
1996 Atlanta Paralympic Games, Atlanta, Georgia
Contact: Tel: 404-588-1996

1997

February 13-18, 1997 American Academy of Orthopedic Surgeons Annual Convention (AAOS), San Francisco, California
Contact: AAOS, 6630 North River Rd., Rosemont, IL 60018-4226; Tel: 708-823-7186; Fax: 708-823-8031

August 31-September 5, 1997 8th World Congress of the International Rehabilitation Medicine Association IRMA, Kyoto, Japan
Contact: Japan Convention Services, Inc., Nippon Press Center Bldg., 2-1, 2-chome, Uchisaiwai-cho, Chiyoda-ku, Tokyo 100, Japan

AUTHOR AND TITLE INDEX

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